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Part VI

Environmental Protection Agency

Ethylene Bisdithiocarbamates (EBDCs); Notice of Intent to Cancel and Conclusion of Special Review

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/18D; FRL 4045-8]

Ethylene bisdithiocarbamates (EBDCs); Notice of Intent to Cancel; Conclusion of Special Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final determination; Notice of Intent to Cancel; Notice of Intent to deny applications for registration.

SUMMARY: This Notice concludes the Special Review and risk/benefit analysis of the EBDCs and announces EPA's intent to cancel registrations and to deny applications for registration for all pesticide products containing EBDCs as an active ingredient unless the registrations/applications comply with the terms and conditions of registration set forth in this Notice. This action is based on the Agency's determination that use of the EBDCs without such modified terms and conditions will result in unreasonable adverse effects to humans or the environment. In summary, EPA is announcing its intent to cancel any EBDC product registration bearing one or more of the following food uses of EBDCs: apricots, carrots, celery, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, and turnips. In addition, EPA is announcing its intent to cancel EBDC products registered for other uses unless certain label modifications are made.

DATES: Requests for a hearing by a registrant, applicant, or other adversely affected party must be received on or before April 1, 1992 or, for a registrant or applicant, within 30 days from the receipt of this Notice, whichever occurs later.

ADDRESSES: Requests for a hearing must be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Additional information supporting this action is available for public inspection at the EBDC docket (docket number "OPP-30000/18D") from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays in the: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, room 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: By mail: Kathleen Martin, Special Review Branch, Special Review and Reregistration Division (H7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office Location and Telephone Number: 3rd Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. Telephone: (703) 308-8024.

SUPPLEMENTARY INFORMATION: This Notice announces EPA's intent to cancel all registrations and deny applications for registration of pesticide products containing ethylene bisdithiocarbamates (EBDCs) as the active ingredient (a.i.) unless the registrants amend their registrations to comply with the terms and conditions set forth in this Notice. This Notice concludes EPA's administrative Special Review of the risks and benefits of the EBDCs which was initiated in a **Federal Register** notice of July 17, 1987 (52 FR 27172). A Notice of Preliminary Determination (PD 2/3) concerning the EBDCs was published in the **Federal Register** on December 20, 1989 (54 FR 52158), and supporting documents including the Technical Support Document for the PD 2/3 were made available to any requesting party at that time. EPA has evaluated the issues raised in the preliminary documents listed above in the light of comments and additional data received during the Special Review process. In summary, EPA is requiring that registrants amend their registrations to delete certain food uses from their labels. For certain retained uses, EPA is requiring that use patterns be amended. The Agency is also requiring that labels be amended to require protective clothing for industrial and agricultural workers. Furthermore, a label hazard warning statement is being required on homegarden-use labels as well as clothing and hygiene language.

This Notice is organized into nine units. Unit I is an introduction providing background information on the EBDCs, EPA actions prior to this Notice, and the legal basis for these actions. Summarized in Unit II is the toxicological data base for the EBDCs. Units III and IV present EPA's assessment of dietary and occupational/homegardener exposure to the EBDCs and their respective risks. Summarized in Unit V is the final benefits assessment on the EBDCs. Comments received from interested parties on specific risk and benefit issues are presented with EPA's response in the appropriate units (II through V). Unit VI includes the comments of the Scientific Advisory Panel and the Secretary of Agriculture on the regulatory actions previously proposed by EPA in its preliminary determination concerning the EBDCs issued December 20, 1989, and EPA's response to those comments. Additionally, the Agency presented certain scientific issues regarding the EBDCs to the SAP in September 1991. The SAP's comments and the Agency's response are included. Described in Unit VII is EPA's risk/benefit assessment and final determination regarding the EBDCs and the actions required by this Notice. Unit VIII provides the procedures for implementing the actions required by this Notice, as well as the procedures for requesting a hearing. Unit IX lists references used in concluding this Special Review of the EBDCs.

I. Introduction

The ethylene bisdithiocarbamates (the EBDCs) are a group of fungicides consisting of mancozeb, maneb, metiram, and nabam. All registrations for a fifth EBDC, zineb, have been cancelled, and therefore, zineb was not considered in this Final Determination. These pesticides are intended for use to protect a wide variety of fruit and vegetable crops against fungal pathogens. The EBDCs also have several non-food agricultural uses including ornamental plants, turf, and soil treatment. Industrially, certain EBDC products are registered for use as antimicrobials in water cooling systems (towers and airwashers), oil well drilling rigs, and in pulp, paper, and sugar mills.

The technical materials are produced by Atochem North America (maneb); BASF Corporation (metiram); Rohm and Haas Company (nabam and mancozeb); and E.I. DuPont de Nemours Company Inc. (mancozeb). These producers/registrants of EBDCs formed the EBDC/ETU Task Force to generate data to support the continued registration of selected uses of the EBDCs.

In the United States, usage of the EBDCs is estimated at about 8 to 12 million pounds of active ingredient (a.i.) per year. The predominant use is on apples, cucurbits (i.e., cucumbers, melons, and squash), lettuce, onions, potatoes, small grains, sweet corn, and tomatoes. The pesticide products containing EBDCs are most commonly formulated as wettable powders, flowables, dry flowables, dusts, and emulsifiable concentrates.

In December 1989, EPA proposed to cancel 45 of the 55 registered food uses of the EBDCs. At the same time, the Agency also encouraged the regulated community and especially grower groups to become more involved in the Special Review process by providing information to the Agency on the benefits of EBDCs, risk reduction measures, and actual use practices.

A number of grower organizations responded to EPA's call for data by providing significant benefits and risk reduction information. Most of the provided benefits information was incorporated into the EBDC benefits assessment. Because of the growers' involvement in the Special Review for the EBDCs, the Agency was able to identify certain benefits that may have otherwise been overlooked. For example, EPA was not aware of the limitations posed by the alternative fungicide registered for use on papaya.

EPA appreciates the growers' efforts to supply residue data under a short time-frame. Most of the residue data submitted by the grower groups were used by the Agency as supplemental information in the exposure assessment, except for the International Apple Institute (IAI) and Hawaiian Papaya Growers data which were used as primary sources of data. Even though submitted residue data were generally not used as the primary source in estimating residues due to their limitations, they were still valuable to the Agency. Food and Drug Administration monitoring data were important in corroborating market basket data. Further, certain grower groups submitted handling and use practice information (e.g., washing and processing studies) that the Agency was able to use in estimating reduction of residues upon processing.

Grower groups that provided information include: the American Dehydrated Onion and Garlic Association, EAK AG INC., California Tomato Growers Association, Florida Farm Bureau Federation, Florida Fresh Fruit and Vegetable Association, Florida Tomato Industry Association, Hawaii Banana Industry Association, Hawaii Papaya Industry Association, International Apple Institute, International Banana Association, Michigan Farm Bureau, Midwest Food Processors Association (MWFPA), National Cotton Council, National Food Processors Association, National Potato Council, New England Fruit Growers' Council on the Environment, Northeastern Apple Growers, Northeast Fruit Growers, Northwest Food Processors Association, Pioneer Hi-Bred International, South Bay Growers, and Southern Frozen Foods, as well as numerous individual growers (Refs. 1 through 6).

The specific benefits and residue data provided by grower groups are detailed in the relevant sections of Units III (Dietary Exposure and Risk) and Unit V (Summary of Benefits Assessment).

A. Regulatory History

1. *Rebuttable Presumption Against Registration.* In 1977, the Agency initiated a Rebuttable Presumption Against Registration (RPAR) and Continued Registration of Pesticide Products Containing EBDCs. This action initiated what is now called the Special Review process. The need for a Special Review of the EBDCs was based on evidence suggesting that the EBDCs and ethylenethiourea (ETU), a common contaminant, metabolite, and degradation product of these pesticides, posed three potential risks to humans and/or the environment: carcinogenicity, developmental toxicity, and acute toxicity to aquatic organisms. Three additional areas of concern were identified as thyroid toxicity, mutagenicity, and skin sensitization.

In 1982, the Agency concluded this Special Review by issuing a Final Determination (PD 4) which required risk reduction measures to prevent unreasonable adverse effects pending development of additional data needed to better assess the risks. The Agency concluded that the potential risk of acute toxicity to aquatic organisms could be reduced through the addition of a label statement warning users of hazards to fish and that potential risks of developmental and thyroid effects to applicators could be adequately reduced by requiring protective clothing. Potentially high dietary exposure resulting from consumption of EBDC-treated home-grown produce was addressed by a label statement highlighting preharvest intervals on labels of home-use products. The Agency also concluded that there were insufficient exposure data to reach any regulatory conclusions regarding the potential risk of carcinogenic effects to humans. Additional data were required to be submitted to address mutagenic effects. The skin sensitization effect was determined not to meet the criteria for an RPAR.

All registrations of products containing zineb (a fifth EBDC) were voluntarily cancelled in 1991. Amobam (a sixth EBDC) was voluntarily cancelled several years ago.

2. *Initiation of Special Review (PD 1).* On July 17, 1987, EPA issued a second Notice of Initiation of Special Review (52 FR 27172) of the EBDC pesticides because of concerns over carcinogenic, developmental, and thyroid effects caused by ETU. The Agency had determined that the registrations containing the EBDC pesticides met or exceeded the risk criteria in 40 CFR 154.7(a)(2) and 154.7(a)(6) relating to carcinogenicity to humans from dietary exposure and a risk to mixer/loader/applicators for carcinogenic, developmental, and thyroid effects. Specifically, EPA determined that exposure to the EBDCs resulted in an increased incidence of thyroid follicular cell adenomas and adenocarcinomas in rats, and liver tumors in two strains of mice. The Notice invited comments from the registrants as well as from the public.

In March 1989, Rohm and Haas, the sole registrant of nabam, requested voluntary cancellation of all agricultural uses. The uses of nabam in sugar mill grinding, crusher, and diffuser systems were retained.

The Agency issued a Data Call-In (DCI) for the EBDCs under FIFRA section 3(c)(2)(B) on March 10, 1989, (Ref. 7) to obtain data to better estimate the risks and benefits involved in the use of these pesticides. The data required by the Notice included residue monitoring data, tank-mix stability data, dermal exposure data, dermal absorption data, reentry data, and benefits data.

On September 6, 1989, the 4 technical registrants of mancozeb, maneb, and metiram (Rohm and Haas, DuPont, Atochem, and BASF) requested that the Agency amend their registrations to delete 42 of the 55 registered food uses and to restrict formulation of their technical products only into products labeled for the retained uses. These amendments were approved on December 4, 1989 (54 FR 50020). The 13 uses to remain on affected EBDC labels were: almonds, asparagus, bananas, caprifigs, cranberries, grapes, onions, peanuts, potatoes, sugar beets, sweet corn, tomatoes, and wheat. Specific crops permitted on labels for the individual EBDCs were: maneb (almonds, bananas, potatoes, sugar beets, sweet corn); mancozeb (asparagus, bananas, cranberries, figs, grapes, onions, peanuts, potatoes, sugar beets, sweet corn, tomatoes, wheat); and metiram (potatoes).

3. *Notice of Preliminary Determination (PD 2/3).* EPA issued a Notice of Preliminary Determination on December 20, 1989 (54 FR 52158), announcing its proposed decision to cancel the 42 uses deleted by the technical registrants on the basis of unacceptable risk and a lack of support by the registrants. The registrants' deletion of 42 of 55 food uses from their registrations decreased the estimated carcinogenic dietary risk of EBDCs from 3×10^{-4} to 2×10^{-5}. The estimated cumulative benefit of EBDC use on the 13 remaining crops was $14 to $27 million. EPA considered the estimated

dietary risk following the registrants' action and concluded that the aggregate long-term risk was still unreasonable. Therefore, EPA proposed to cancel the use of mancozeb, maneb, and metiram on 3 additional crops (bananas, potatoes, and tomatoes) and retain only the use of mancozeb and maneb on 10 of the 13 crops (almonds, asparagus, caprifigs, cranberries, grapes, onions, peanuts, sugar beets, sweet corn, and wheat). The estimated carcinogenic dietary risk resulting from the 10 retained crops was 3×10^{-6} and estimated benefits were $13 to $26 million.

In the PD 2/3, the Agency proposed a label language requirement that agricultural workers applying EBDC pesticides wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, shoes, socks, and goggles or a face shield. Additionally, the proposed label would require agricultural workers to wear a chemical-resistant apron during mixing and loading. For agricultural workers applying EBDCs in completely enclosed cabs with positive pressure filtration, or aerially with an enclosed cockpit, a long-sleeved shirt and long pants were proposed to be allowed to be worn in place of the protective clothing described above. Chemical-resistant gloves were to be available in the cab or cockpit and worn upon exiting. During aerial application, human flaggers were to be prohibited unless in totally enclosed vehicles. With incorporation of the above-mentioned protective clothing requirements, developmental and thyroid Margins-of-Exposure (MOEs) for workers using EBDC products on most agricultural sites increased to greater than 100 except for the use of maneb on grapes and ornamentals. EPA proposed to cancel these two maneb uses after determining that the estimated risks of continued use exceeded the estimated benefits.

The Agency also proposed a label language requirement establishing an interim reentry interval of 24–hours for all EBDC products used on agricultural sites because of concern about EBDC and ETU exposure to workers reentering treated fields for the purposes of hand harvesting, pruning, and weeding.

For homeowners, the Agency proposed a label language requirement that homeowners applying EBDC pesticides wear a long-sleeved shirt, long pants, and rubber gloves. The Agency did not believe that additional protective clothing requirements for homeowners beyond that proposed would be an effective means of reducing risks because the Agency believes that homeowners will not go to the expense of purchasing or wearing protective clothing. Therefore, EPA proposed to cancel the use of maneb on turf by homeowners where MOEs remained under 100 even with a long-sleeved shirt, long pants, and gloves and estimated risks of continued use outweighed the estimated benefits. In addition, the Agency proposed to cancel homeowner use of mancozeb on fruit trees and turf, and homeowner use of maneb on vegetables, ornamentals, fruit trees, and turf because of concerns about cancer risks which exceeded 10^{-6} for homeowners applying EBDCs.

Finally, the Agency proposed a label language requirement that all industrial workers applying EBDC pesticides wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, shoes, socks, and goggles or a face shield. However, even assuming incorporation of these protective clothing requirements, the MOEs for thyroid effects for nabam used in paper mills and sugar mills remained below 100. Therefore, after determining that the risks outweighed the benefits of use, the Agency proposed cancellation of the use of nabam in paper mills and sugar mills.

4. *Conclusion of Special Review (PD 4).* EPA's assessment and final decision regarding the risks and benefits associated with products containing the EBDCs are set forth in this document. The Agency has received additional data and comments in response to the EPA's EBDC Preliminary Determination.

Based on information received in response to the PD 2/3, the Agency has determined that the dietary risks exceed the benefits for the following food uses of EBDCs: apricots, carrots, celery, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, and turnips. Accordingly, EPA is announcing its intent to cancel all mancozeb, maneb, and metiram products registered for one or more of those 11 uses. Additionally, EPA intends to cancel products registered for certain other agricultural uses unless their registrations and labels are amended to reflect the changes in use patterns specified herein. For workers, protective clothing measures are required to avoid cancellation. Also, a 24–hour interim reentry interval will be established. The Agency also intends to cancel all mancozeb products registered for use on homegarden fruit trees and turf. Clothing and hygiene language will be required on homegarden-use labels and registrations. A more detailed discussion is included in the appropriate Units of this document along with EPA's responses to comments received.

B. Legal Background

Before a pesticide product may be lawfully sold or distributed in either intrastate or interstate commerce, the product must be registered by the Agency [FIFRA sections 3(a) and 12(a)(1)]. A registration is a license allowing a pesticide product to be sold and distributed for specified uses in accordance with specified use instructions, precautions, and other terms and conditions.

To obtain a registration for a pesticide under FIFRA, an applicant must demonstrate that the pesticide satisfies the statutory standard for registration. The standard requires, among other things, that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment," (FIFRA section 3(c)(5)). The term "unreasonable adverse effects on the environment" is defined in FIFRA section 2(bb) as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." This standard requires a finding that the benefits of the use of the pesticide exceed the risks of use when the pesticide is used in compliance with the terms and conditions of registration or in accordance with commonly recognized practices.

The burden of proving that a pesticide satisfies the statutory standard is on the proponents of registration and continues as long as the registration remains in effect. Under FIFRA section 6, the Administrator may issue a Notice of Intent to Cancel the registration of a pesticide product whenever it appears to the Administrator that the pesticide product causes unreasonable adverse effects on the environment. The Agency created the Special Review process to facilitate the identification of pesticide uses which may not satisfy the statutory requirements for registration and to provide an informal procedure to gather and evaluate information about the risks and benefits of these uses.

A Special Review may be initiated if a pesticide meets or exceeds the risk criteria set out in the regulations at 40 CFR part 154. The Agency announces that a Special Review is initiated by issuing a notice in the **Federal Register**. Registrants and other interested persons are invited to review the data upon which the Special Review is based and to submit data and information to rebut the Agency's conclusions by showing that the Agency's initial determination

was in error, or by showing that use of the pesticide is not likely to result in any significant risk to human health or the environment. In addition to submitting rebuttal evidence, commenters may submit relevant information to aid in the determination of whether or not the economic, social, and environmental benefits of the use of the pesticide outweigh the risks of use. After reviewing the comments received and other relevant material obtained during the Special Review process, the Agency makes a decision on the future status of registrations of the pesticide.

The Special Review process may be concluded in various ways depending upon the outcome of the Agency's risk/benefit assessment. If the Agency concludes that all of its risk concerns have been adequately rebutted, the pesticide registration will be maintained unchanged. If, however, all risk concerns are not rebutted, the Agency will proceed to a full risk/benefit assessment. In determining whether or not the use of a pesticide poses risks which are greater than its benefits, the Agency considers possible changes to the terms and conditions of registration which can reduce risks, and the impacts of such modifications on the benefits of use. If the Agency determines that such changes reduce risks to the level where the benefits outweigh the risks, it may require that such changes be made in the terms and conditions of the registration. Alternatively, the Agency may determine that no changes in the terms and conditions of a registration will adequately assure that use of the pesticide will not pose any unreasonable adverse effects. If the Agency makes such a determination, it may seek cancellation, and if necessary, suspension. In either case, the Agency must issue a Notice of Intent to Cancel the registrations. If the Notice requires changes in the terms and conditions of registration, cancellation may be avoided by making the specified changes set forth in the Notice, if possible. Adversely affected persons, including registrants and applicants for registration, may also request a hearing on the cancellation of a specified registration and use, and if they do so in a legally effective manner, that registration and use will be continued pending a decision at the close of an administrative hearing.

II. Summary of Toxicological Concerns and Agency Evaluation of Comments and Additional Data

The Special Review of the EBDCs was initiated in 1987 because of carcinogenic, developmental, and thyroid effects caused by ethylenethiourea (ETU). Summarized in this Unit are the Agency's review of studies for these effects including discussions of new information and public comments that have been received since the Notice of Preliminary Determination (PD 2/3) was issued in December 1989.

A. Carcinogenicity

1. *Hazard identification.* In the PD 2/3, the Agency relied on data from four studies in its carcinogenic risk assessment of ETU. In one study (Ref. 8), marked increases in liver tumors (hepatomas) were observed in mice fed 646 parts per million (ppm) of ETU daily for 80 weeks. The thyroids in this study were not examined. Another study (Ref. 8) showed that rats fed two different doses of ETU (175 or 350 ppm) daily for 18 months developed thyroid carcinomas at both dose levels. No thyroid tumors developed in controls. In a third study (Ref. 8), thyroid effects were observed in rats fed ETU at doses of 5, 25, 125, 250, or 500 ppm for nearly 2 years. A dose-related increase in thyroid follicular cell carcinomas and adenocarcinomas was observed at 250 and 500 ppm; thyroid follicular cell adenomas at 250 ppm; and thyroid follicular cell hyperplasia at 5, 25, 125, and 250 ppm.

At the time the PD 2/3 was issued, the National Toxicology Program (NTP) made available to the Agency a fourth study (Ref. 8) that included data from ETU carcinogenicity studies conducted with rats and mice. The NTP studies were of an unusually complex design when compared with the usual NTP carcinogenicity bioassay where the dosing of animals is started only after weaning. In the ETU bioassay, some groups of animals were exposed to ETU in utero and fed ETU after weaning throughout their lifetime. In the mouse study, for example, the doses for the parent animals were 0, 33, 110, and 330 ppm, and the lifetime doses for the test animals after weaning were 0, 100, 330, and 1,000 ppm. However, because the data for animals exposed in utero were still under review, the Agency limited its analysis in the PD 2/3 dose response assessment to those animal groups which were exposed in the standard fashion (i.e., were not exposed in utero or through milk but were put on the ETU-containing diets only after weaning).

In the NTP mouse study using the standard treatment groups, animals were fed doses of 0, 333, or 1,000 ppm ETU in the diet for up to 2 years. In the female mice treated at the low dose, 30 percent of the animals exhibited liver adenomas only, while an additional 58 percent showed liver carcinomas for a combined total of 88 percent showing adenomas or carcinomas. At the high dose, only 2 percent exhibited adenomas while 96 percent were diagnosed with carcinomas. This contrasts sharply with a total of only 8 percent of the females in the control group exhibiting either adenomas (4 percent) or carcinomas (4 percent).

The thyroid gland in female mice showed dose-related increases in follicular cell hyperplasia when compared to controls (4 percent, 26 percent, and 94 percent, respectively). Male mice showed follicular cell hyperplasia only at the high dose tested (0 percent, 0 percent, and 88 percent, respectively). Female mice showed statistically-significant increases in follicular cell multiple adenomas and carcinomas at the high dose only. No thyroid carcinomas or adenomas were observed in controls. In males, follicular cell adenomas and carcinomas appeared to a greater extent in the high dose group total (62 percent) than in controls (2 percent) or the low dose group (2 percent).

In the NTP bioassay conducted on rats, the thyroid gland was the principal target organ for ETU. Animals were fed ETU in their diet at levels of 0, 83, or 250 ppm for up to 2 years. Hyperplasia ranged between 0 and 9 percent for control groups, whereas hyperplasia in all treated groups was between 18 and 64 percent. Follicular cell adenocarcinomas occurred in 58 percent of the high dose group of males compared to 2 percent in controls. In females, it was 16 percent for adenocarcinomas at the high dose compared with 4 percent for controls.

The potency factor (Q_1^*) used in the PD 2/3, 0.6 $(mg/kg/day)^{-1}$, was based on female mouse liver tumors observed in the NTP study on ETU. Although NTP data on the rat thyroid were also available to the Agency to estimate a revised Q_1^*, the mouse data were chosen because they provided a slightly more conservative Q_1^* than that estimated for the male rat thyroid. Also, there was no developed plausible mechanistic information to suggest a mode of action for liver tumors in the mouse as there was for thyroid tumors in the rat (See Unit II.A.4. for further discussion).

2. *Potency factor (Q_1^*) issues—a. EBDC/ETU Task Force analysis.* In December 1990 and April 1991, the EBDC/ETU Task Force submitted to EPA an analysis of the female mouse liver data from the NTP study (OPP 30000/53: D–12412A and D–12639A). This analysis had been conducted by

three independent statisticians. Their analysis argued that the preliminary cancer potency factor (Q_1^*) of 0.6 $(mg/kg/day)^{-1}$ should be reduced. The approach used in reaching this conclusion differed from the Agency's in three ways:

(1) Actual body weight and food consumption data from the NTP study were used by the Task Force (instead of standard conversion values derived empirically) in converting the estimated potency per ppm in food to an estimated potency per mg/kg/day, thereby reducing the potency factor by about 20 percent.

(2) Female mouse tumor response data for pre-weaning dose groups receiving the same post-weaning dose were combined or pooled by the Task Force (i.e., liver tumor responses were summed/pooled), because there were no statistically-significant differences between mice exposed in utero and the standard dose groups. However, as a result of the inclusion of the low 33/100 ppm dose group (i.e., pre-weaning dose/post-weaning dose) from the in utero exposure group as a data point, the high dose group (1,000 ppm) was omitted by the Task Force from the linearized multistage model used to calculate the Q_1^*. This was done because the Task Force suggested it allowed for a better definition of the shape of the dose-response curve in the lower dose region, which is of primary interest for quantitative risk assessment purposes. This reduces the Q_1^* estimate by about 4.5 fold.

(3) An interspecies scaling factor was based upon the ratio of human to animal body weights raised to the ¼ power rather than the ⅓ power currently used by the Agency. This recommendation was motivated by the work of Travis and White (1988) and O'Flaherty (1989) as well as by indications that certain Federal Government agencies are considering changing from ⅓ power to ¼ power. This reduces the Q_1^* by a factor of about two.

The consequence of some or all of these changes would make the preliminary Q_1^* used in the PD 2/3, based on female mouse liver tumors, lower than the Q_1^* based upon the male rat thyroid tumors.

b. *HED Peer Review*. On May 29, 1991, the Agency's Office of Pesticide Program's, Health Effects Division Carcinogenicity Peer Review Committee met to discuss these Q_1^* issues (Ref. 9). The Committee concluded the following:

(1) The Q_1^* value should be estimated with the initial inclusion of all four dose groups (i.e., 0, 100, 330, 1,000 ppm).

(2) The experimental dose of 33/100 ppm for the female mouse liver should be included as a data point in estimating the Q_1^*. Also, the liver tumor response in female mice receiving their first exposure as adults after 8 weeks of age should be combined (pooled) with those female mice receiving their initial exposure in utero which then continued uninterrupted throughout the remainder of their life-span.

(3) The interspecies scaling factor based upon the ratio of human to animal body weights raised to the ⅓ power should be employed. This is consistent with Agency policy.

(4) The best fit of the data to the linearized multistage model (with the possible elimination of the high dose) to obtain the best estimate of risk at the low dose should determine the Q_1^*.

(5) Actual body weight and food consumption data should be used.

c. *Inclusion of the low dose.* The most significant deliberation within the HED Peer Review Committee focused on the inclusion of the 33/100 ppm low dose group and the exclusion of the 1,000 ppm dose group for the purpose of dose response assessment. The inclusion of the 33/100 ppm dose was accepted by the Peer Review Committee; however, there were strong arguments for excluding the 33/100 ppm dose from the Q_1^* determination. The arguments for including the data point were based primarily on biological considerations, thereby allowing the lowest dose treatment group to provide a better estimate and extrapolation to the events occurring at low dose exposures. The arguments for not including this data point were based primarily on statistical incongruities of the experimental design (small sample size and the absence of any corresponding control group). Due to strong arguments against including this data point, the Agency requested comments from the FIFRA Scientific Advisory Panel (SAP) relative to the Peer Review Committee's recommendations for appropriate use of this dose group for risk characterization. Specifically, the second gathering of the SAP (convened on September 18, 1991) was asked to provide, to the extent possible, the scientific arguments for either inclusion or exclusion of the low dose data point in the dose-response assessment.

In an October 2, 1991 report, the SAP stated that adequate data should always be included unless there is a strong reason to exclude them. The Panel felt strongly that the data from the 33/100 ppm group should be included in the analyses. The SAP's argument for inclusion was that the Agency's standard dose-response formula (e.g., linearized multistage model) is probably not statistically appropriate for use in calculating the Q_1^* if all data except the control show over 90 percent rates of cancer incidence. The Panel also believed that, in this case, there is a strong reason for the Agency's standard approach to exclude the highest dose group because its inclusion is associated with gross distortion of estimates of the probable effects at lower doses when used in the linearized multistage model. The Panel's complete response can be found in Unit VI of this Notice.

d. *Q_1^* for the final determination.* As a result of the HED Peer Review Committee decisions and the recommendations of the SAP, the revised Q_1^* for the Final Determination of the EBDCs/ETU reflects inclusion of the low dose group and is estimated to be 0.11 $(mg/kg/day)^{-1}$ (Ref. 10).

3. *Mutagenicity*. ETU and the EBDCs have been tested for mutagenicity in several assay systems (Ref. 8). It is well recognized that a correlation exists between genotoxic agents and carcinogenicity; many, but not all, mutagenic agents contribute to or induce tumor formation. Although the results of available studies were both positive and negative, the body of evidence suggests that ETU and the EBDCs are capable of inducing a variety of genotoxic endpoints. These include responses in gene mutation assays, structural chromosomal assays, and other genotoxic effects. ETU does not appear to be a highly potent genotoxic agent; however, the positive mutagenicity findings generally support the carcinogenic observations of ETU in both rats and mice.

4. *Non-genotoxic tumor formation (Threshold Concept).* There is experimental evidence that thyroid tumors in rats can only occur as a result of exceeding a threshold (i.e., tumors appear only when hormone concentrations exceed a specific level, identified as the threshold, for an extended period of time). To fully understand the threshold concept, it is necessary to provide a brief explanation of the physiological relationship between the pituitary gland and thyroid gland. Decreased levels of thyroid hormones threaten the physiological equilibrium which causes the anterior pituitary gland to secrete thyroid stimulating hormone (TSH). In turn, the TSH causes thyroid hormone levels to rise back to normal levels. The anterior pituitary then decreases production of TSH which causes a subsequent decrease in the production of thyroid hormone. If there is a disruption of this feedback mechanism resulting in decreased thyroid hormone levels that cannot be counterbalanced by increased

TSH production, the result is the continuous but futile stimulation of the thyroid by TSH. This constant stimulation by TSH over an extended period of time changes the morphology of the thyroid gland and, at some critical point, results in tumor formation (i.e., follicular cell neoplasia). This would result in a mechanism for tumor formation involving a threshold. It is unclear, though, how the "weak" genotoxicity of ETU may play a role in this process.

Iodide peroxidase is an enzyme that is essential in the production of thyroid hormones. ETU is structurally related to several chemicals that inhibit the production of iodide peroxidase and has been demonstrated to inhibit iodide peroxidase *in vitro*. ETU would be expected to have the same effect on the thyroid gland *in vivo*. Thus, ETU may interfere with the biosynthesis of thyroid hormones by inhibiting iodide peroxidase which results in the positive feedback to the pituitary (described above) for as long as ETU is sufficiently available to maintain decreased thyroid hormone levels. It has been argued, therefore, that unless dose levels of ETU are at high enough levels to sufficiently inhibit iodide peroxidase for an extended period of time, causing the appropriate hormone levels to exceed a specific concentration (i.e., the threshold), ETU should not cause thyroid tumors. In other words, the dose of ETU below the threshold will be too low to cause this exaggerated positive feedback.

EPA presented the threshold concept to the Agency's FIFRA Scientific Advisory Panel on May 15, 1990. In general, the Panel believes that there is a reasonable basis to postulate a mode and mechanism of action for the thyroid tumor effects but was unable to provide a plausible explanation for the formation of liver tumors as a result of elevated levels of TSH or decreased circulating levels of thyroid hormones. The Panel's complete response can be found in Unit VI of this document.

5. *Weight-of-evidence for carcinogenicity.* EPA classified ETU as a Group B_2 Carcinogen by using a weight-of-the-evidence approach and following the classification scheme set forth in EPA's Carcinogenic Risk Assessment Guidelines (51 FR 33992). In general terms, a B_2 classification means that the weight-of-evidence from laboratory animal data is sufficient to consider the compound a probable human carcinogen. Evidence is sufficient if there is an increased incidence of tumors: (a) In multiple species or strains of test animals; or (b) in multiple experiments, for example, with different dose levels or routes of administration; or (c) to an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset.

ETU's B2 classification is based on evidence that:

(1) ETU induced an increased incidence of thyroid follicular cell adenomas and adenocarcinomas in mice and 2 strains of rats (3 separate studies) and an increased incidence of liver adenomas and carcinomas in 3 strains of mice.

(2) ETU induced thyroid tumors in rats after 1 year or less of treatment.

(3) ETU induced a high incidence of both thyroid tumors in rats and hepatomas in mice to an unusual degree in a single experiment.

(4) ETU is structurally similar to several other thyroid inhibitors (e.g., thiouracil and thiourea) that have been found to induce liver and/or thyroid tumors in rodents.

(5) Results of the available mutagenicity studies on ETU also provide supportive evidence of the carcinogenic effect.

B. Developmental Effects

The no-observable-adverse-effect level (NOAEL) for developmental toxicity resulting from exposure to ETU is equal to or less than 5.0 mg/kg/day based on a rat study (Ref. 8). Although a no-observable-effect level (NOEL) was not established in the rat study, the Agency believes the NOAEL is close to the NOEL and could be used for the purpose of estimating Margins-of-Exposure (MOEs). ETU was shown to be developmentally toxic at dose levels lower than those that produced no apparent maternal toxicity. At 5.0 mg/kg/day, which was the lowest dose tested, developmental toxicity was observed in the form of delayed ossification or hardening of the parietal bone (in the skull). Delayed ossification was clearly dose-related and at higher rates than in controls and appears to be a sensitive indicator of exposure to ETU. ETU has also been detected in term fetuses at concentrations comparable to those found in maternal tissues following oral treatment and it could therefore not be determined whether or not the malformations arose as a result of direct action on the fetus or indirectly by altering maternal thyroid or other functions. The results of the NTP study conducted on rats and mice indicated that ETU affected thyroid function in both species. However, a mouse study showed no developmental toxicity at very high doses (800 mg/kg/day by gavage). Therefore, simple inhibition of the thyroid gland may not necessarily be the mechanism by which developmental effects are manifested in rats. Preliminary evidence in the literature indicates developmental effects in rabbits.

C. Thyroid Effects

ETU has been shown to cause thyroid effects from subchronic exposures. A 90–day study on rats revealed a NOEL of 5 ppm (0.25 mg/kg/day) (Ref. 8). Thyroid toxicity seen at levels above 5 ppm consisted of thyroid hyperplasia, decreased uptake of radioactive iodine by the thyroid, and decreased serum levels of triiodothyronine (T3) and tetraiodothyronine (T4). This 90–day rat study also indicated a lowest-effect level (LEL) of 25 ppm (1.25 mg/kg/day). A 3,000–fold uncertainty factor was applied to the LEL to derive the reference dose which is 0.00008 mg/kg/body weight/day. The uncertainty factor of 3,000 accounts for inter/intraspecies extrapolation (x 100), the lack of a NOEL (x 10), and data gaps (x 3).

D. Other Effects

Although ecological effects are not a subject of this Special Review, the Agency is concerned about these effects as well as the potential for the EBDCs to contaminate groundwater.

1. *Ecological effects.* In the PD 2/3, EPA stated that additional data would be needed to more fully assess the potential of EBDCs to cause reproductive effects in birds and chronic and acute toxicity in aquatic organisms. The Agency has reviewed the data that were submitted after publication of the Registration Standards for mancozeb, maneb, metiram, and nabam. Summaries of new findings for each chemical are as follows (Ref. 11):

(a) Repeated applications of mancozeb on apples and potatoes may pose a reproductive risk to birds.

(b) Repeated applications of maneb on apples and cranberries may pose a reproductive risk to birds. Freshwater fish are at approximately five times greater acute risk than originally thought based on new data; freshwater fish may also be at chronic risk from repeat applications; estuarine invertebrates are the most sensitive of all aquatic species.

(c) For nabam industrial uses, estuarine invertebrates are more at risk than previously noted.

(d) Repeated applications of metiram on apples may pose reproductive risk to birds.

The following data requirements remain outstanding: aquatic toxicity and avian reproduction studies for mancozeb (currently in review), maneb

(due 7/92 and 11/92), and metiram (due 4/92 and 12/92). Additional environmental fate data are also required to fully address the ecological concerns. However, the limited environmental fate data base indicates that the EBDCs rapidly degrade to ETU. This rapid degradation mitigates potential concern for the parent EBDC. Further testing requirements for ETU may be required depending on the results of the review of environmental fate studies required by the Registration Standards.

2. *Groundwater.* The Agency required retrospective groundwater monitoring studies for each of the EBDC parent compounds in 1986 through Data Call-In Notices and Registration Standards. These Data Call-In Notices were issued in response to environmental fate data submitted by EBDC registrants in response to the 1984 Data Call-In Notice which indicated that ETU has the potential to leach to groundwater. The registrant for metiram submitted a protocol for the small-scale retrospective groundwater monitoring study in 1990. This protocol was rejected by the Agency because it was too general and lacked detailed information such as the criteria and procedures for the selection of the test sites, well locations, analytical methods and limits of detections for the parent compound and ETU, and quality assurance/control programs. As of this date, no groundwater monitoring for ETU or the EBDC compounds has begun.

The National Pesticide Survey (NPS), started by EPA in 1985, was the first study to analyze for pesticides and nitrates in drinking water wells on a national level. The survey reported a detection of ETU in one well (16 ppb at a 4.5 ppb limit of detection) out of 739 rural domestic wells. ETU was not detected in any of the 556 community water systems tested. Statistically, 0.1 percent of rural domestic wells (or 8,470 rural domestic wells in the United States) would be expected to be contaminated with ETU. To date, the Agency has not established a Maximum Contaminant Level (MCL) or a Health Advisory (HA) for ETU.

E. Comments and Response

A number of comments were received in response to the PD 2/3 regarding the toxicity of the EBDC pesticides (Ref 12). A summary of those comments and the Agency's responses follow.

1. *Comment.* One commenter states that there are currently no valid studies which evaluate the effects of EBDCs on humans. While animal studies provide a basis for assuming cancer response in humans, there are significant differences to question the validity of those test results. In particular, the breakdown product of EBDCs, ethylenethiourea (ETU), does not produce the same result on thyroid function in man as it does in a rat. The test results show ETU to be a problem only at doses higher than EPA's estimate of human exposure. The commenter states that it is unreasonable and unfair to extrapolate these doses to assume a significant health risk to humans.

Response. The Agency also is not aware of any valid human epidemiological studies that evaluate the effects of any of the EBDCs or ETU. However, there are grounds to believe that the EBDCs and/or ETU may cause the same cancerous and non-cancerous effects in humans as it does in other mammals by one or more mechanisms. First, EBDCs or ETU may directly act upon the DNA molecule causing a mutation with the subsequent event of carcinogenicity. This cause and effect relationship can be independent of the dose level administered. Second, ETU may also cause an imbalance in thyroid hormone levels which ultimately changes the thyroid gland morphology (follicular cell neoplasia).

2. *Comment.* Another commenter contends that the EBDCs may not be human carcinogens, based upon the article written by Ames and Gold (Science Vol. 249, 31 August 1990) which states that chemicals tested at the maximum tolerated dose (MTD) induce cell division which then plays a dominant role in carcinogenesis. Thus, Ames and Gold conclude that at the MTD a rodent carcinogen provides no information about low-dose risk to man.

Response. The EBDCs and ETU have been tested in cancer bioassays at lower doses than the MTD in more than one species and several experiments with positive results. In the case of EBDCs/ETU, neither the specific mechanism nor the sequence of events which allow for the manifestation of carcinogenesis are known. As stated in the Federal Register (50 FR 10372), EPA's policy is that "in the absence of adequate data on humans, it is reasonable to regard chemicals that are carcinogenic in laboratory animals as if they were also carcinogenic to humans***as a general principle."

3. *Comment.* A commenter has called for positive proof that this family of fungicides and/or its metabolite, ETU, cause cancer in humans.

Response. The Agency is not aware of any valid human epidemiological studies that evaluate effects from ETU or any of the EBDCs. However, the Agency has data on some of the chemicals that show that under certain test conditions carcinogenic effects are manifested. Because EBDCs and ETU have been shown to cause cancer in other mammals, it is reasonable to assume that these chemicals have the potential to cause similar effects in humans. As noted in the previous response, it is EPA policy to utilize animal data to identify potential carcinogenic risks to humans. The Agency does not believe it would be appropriate public policy to ignore such data and wait for positive evidence of human harm before taking any action. The degree of confidence in a chemical's ability or potential to cause cancer in humans, in the absence of human studies, is based primarily upon animal studies and how well the conduct of these studies follow established scientific principles and guidelines. This is the basis for the weight-of-evidence approach that enables the Agency to take the position that these chemicals are probable human carcinogens in the absence of valid human epidemiological studies.

4. *Comment.* A commenter stated that the risk assessment does not include the risk from nitrosated ETU, which may form in the human stomach and has been demonstrated to induce potent genotoxic effects.

Response. The acidity of the rodent stomach is comparable to the acidity of the human stomach, with other gastric constituents being generally comparable. Because of this similarity, one can reasonably assume that whatever chemical reaction occurs in the rodent stomach might also occur in the human stomach. Assuming the nitrosation of the ETU occurs in the rat stomach and results in a tumorigenic effect, this would have already been considered in the determination and selection of the data used to calculate a Q_1^* and subsequent risk analysis.

5. *Comment.* A commenter submitted a research publication which presented data on the mechanism of thyroid peroxidase inhibition by ETU.

Response. The published article presents *in vitro* experimental evidence on a mechanism of action for the inhibition of thyroid peroxidase by ETU and puts forth the argument that the findings provide a biochemical basis for the existence of a no-observable-effect level (NOEL), thereby establishing a threshold level for thyroid carcinogenesis. Even if one assumed that a NOEL existed, it does not necessarily follow that the establishment of a NOEL automatically precludes a genotoxic mechanism for thyroid carcinogenicity. Extensive mutagenicity tests conducted on the

EBDCs/ETU have been interpreted as either weakly positive, equivocal, or negative. Although the article is supportive of a threshold phenomenon, data have not been submitted to the Agency that directly address the carcinogenicity issue of the thyroid by ETU *in vivo*.

6. *Comment.* One commenter indicated that studies have shown cancer and birth defects occurring in rats exposed to massive doses of EBDCs but not occurring in mice, rabbits, and hamsters exposed to the same doses.

Response. ETU, the common metabolite of all the EBDCs, has been shown to produce thyroid tumors in rats and mice and liver tumors in mice. The Agency is not aware of carcinogenicity studies being conducted on rabbits. The studies conducted on hamsters were not scientifically acceptable.

ETU is a teratogen in rats and hamsters although in hamsters at much higher doses than in rats. It does not appear to be teratogenic in mice. Preliminary evidence in the literature indicates developmental effects in rabbits.

Nabam has been shown to produce developmental effects in rabbits at very low dose levels and there is some suggestive, but currently incomplete data, that it also produces developmental defects in rats.

The fact that a chemical can produce a similar type of effect between species or sexes without regard to dose is not biologically unusual. The type and site of the response can be explained by the chemical agent's pharmacokinetics and pharmacodynamics between species. One may assume that a particular response observed in one species has the potential of appearing in one or more additional species in the same or related form if the pharmacokinetics and pharmacodynamics of the agent is altered and the sensitivities between species differ.

III. Dietary Exposure and Risk

A. Dietary Exposure

In the EBDC Preliminary Determination (PD 2/3), the Agency estimated the chronic dietary risk using field trial residue data that reflected use of EBDCs at maximum application rates, minimum preharvest intervals, and at least the typical number of applications. Also considered were commercial processing data for mancozeb, maneb, and metiram in addition to washing, cooking, and other processing studies that were available at that time. For all 55 crops, the total cancer risk from dietary exposure to EBDC-treated crops was estimated to be 3×10^{-4}.

In the PD 2/3, EPA stated its belief that if more representative data were available (i.e., studies that would allow the Agency to estimate average residue levels closer to the dinner plate rather than the farm gate), the dietary risk estimates could be significantly lower and that the Agency might conclude that the risks could possibly be outweighed by the benefits for more crops than the 10 proposed to be retained. On March 10, 1989, the Agency required the EBDC registrants to generate market basket data for representative crops which could then be translated to other similar crops (Ref. 7). Generally, residue data from a particular crop may be translated to other crops within the same crop group (Ref. 19).

The EBDC/ETU Task Force sampled, at randomly selected grocery stores across the United States, various food forms (e.g., raw, canned, frozen, juice) of 12 representative crops: almonds, apples, bananas, broccoli, cucumbers, dry beans, grapes, head lettuce, onions, potatoes, sweet corn, and tomatoes. Also, meat and milk were sampled. The EBDC/ETU Task Force chose not to sample five of the representative crops (carrots, leaf lettuce, peaches, spinach, and succulent beans). Carrots would have been translatable to sugar beets and turnip roots; leaf lettuce to celery, endive, fennel, and rhubarb; peaches to apricots and nectarines; and spinach to collards, kale, mustard greens, and turnip greens. The field trial residue data cited in the PD 2/3 are used in this Final Determination as the basis for residue estimates for these commodities for which market basket data are unavailable.

In September 1990, the EBDC/ETU Task Force submitted market basket data for 8 of the 12 crops: broccoli, cucumbers, dry beans, head lettuce, onions, potatoes, sweet corn, tomatoes, meat, and milk (Ref. 13). In total, 5,784 samples had been taken and analyzed for EBDC and ETU and only 1 sample was reported to have EBDC or ETU residues greater than 1 ppm; most EBDC tolerances are 7 ppm. The average residue levels in samples taken at the grocery stores were significantly lower than the average residue levels previously reported in field trials (i.e., at the farm gate) (Refs. 14 through 18).

For the Final Determination residue estimates, broccoli market basket data were translated to brussels sprouts, cabbage, cauliflower, and kohlrabi; cucumber data were translated to cantaloupe, casaba melons, crenshaw melons, honeydew melons, pumpkin, squash, and watermelon; dry bean market basket data were translated to cotton and peanuts; sweet corn data to barley, field corn, oats, rye, and wheat; and tomatoes were translated to eggplant and peppers.

Market basket data had also been generated for four other sites: almonds, apples, bananas, and grapes. However, due to problems encountered with the Craven Laboratories testing, those data were not used in the dietary exposure estimates. As an alternative, the EBDC/ETU Task Force generated limited monitoring data for bananas (Ref. 20), grape juice (Ref. 21), and wine (Ref. 22); also, some additional residue field trial data were provided for fresh grapes (Ref. 23). For apples, the Task Force submitted residue field trial data developed in cooperation with the International Apple Institute (IAI) in support of a new, more restrictive use pattern (Refs. 1 through 3). For almonds, the Task Force agreed that the Agency should use the PD 2/3 field trial data. Existing field trial data were also used for cranberry and papaya, which were to be supported by the market basket data for grapes and apples, respectively. The available apple residue data were translated to crabapple/quince and pears. The grape juice data were translated to cranberry juice.

Other data considered in refining the PD 2/3 residue estimates for the PD 4 include updated percent-crop treated information, which were obtained in part from the National Agricultural Pesticide Impact Assessment Program (NAPIAP) report (Ref. 24), processing data, and residue information provided by the following studies: FDA and state monitoring data; Florida Special Processing Study (celery, lettuce, pepper, and tomatoes); Hawaii Banana Study; the Hawaiian Papaya Growers' papaya transportation and storage study; Head Lettuce monitoring (wrapped and unwrapped); International Apple Institute apple study; leafy green studies; Midwest Food Processors' residue/processing study; the National Food Processors Association database of member's monitoring results; New England Fruit Growers' residue study in apples from typical uses; and the Northwest Food Processors Association potato data (Refs. 4, 5, and 25 through 32).

B. Carcinogenic Risk

Using the revised residue estimates (which incorporated commercial processing factors, washing and peeling factors, cooking factors, etc.), updated percent-crop treated information, and the revised upper-bound cancer potency factor (Q_1^*), EPA now estimates that the upper-bound lifetime carcinogenic risk for the United States population from

dietary exposure to EBDCs from all 56 crops is 1.8×10^{-5} compared to the PD 2/3 estimate of 3×10^{-4} (Refs. 33 through 35); it appears that there are 56 uses of EBDCs because dry and succulent beans were listed as 1 site in the PD 2/3 and now they are listed as 2 sites. These risk estimates were derived using the Dietary Risk Evaluation System (DRES), the Agency's computerized data base containing food consumption patterns. The DRES can provide dietary exposure and risk estimates for the U.S. population and 22 subgroups of the U.S. population. Two of the most highly exposed subpopulations include non-nursing infants less than 1 year old and children age 1 to 6 years. Estimated carcinogenic risks to infants and children are discussed in Unit VII.A.

Listed in the following Table 1 are the PD 2/3 and PD 4 carcinogenic risk estimates to the overall U.S. population for each of the 56 commodities. The estimates of carcinogenic risk cited in this Notice are upper-bound estimates at the 95 percent confidence level, meaning that there is a 95 percent probability that the true risks do not exceed the estimates, and may be lower. The Agency's Guidelines point out that the use of upper-bound risk estimates is generally appropriate, but that the lower bound of risk may be as low as zero. The Guidelines state: "An established procedure does not yet exist for making 'most likely' or 'best' estimates of risk within the range of uncertainty defined by the upper and lower limit estimates." Thus, upper bound estimates are a prudent approach to risk estimation which may overstate risks, but it is designed to avoid understating them.

TABLE 1.—SUMMARY OF UPPER-BOUND LIFETIME CARCINOGENIC RISK, PERCENT RfD OCCUPIED, AND BENEFITS ESTIMATES.

Crop	PD 2/3 Risk Estimates	PD 4 Risk Estimates	PD 4 Percent RfD Range Occupied	PD 4 Benefits Range	Cost-Effectiveness
Uses to be Retained					
Almonds	7.3×10^{-9}	1.3×10^{-8} (FT)[5]	<1	Not Identified	Not Identified
Apples	1.0×10^{-4}	3.3×10^{-7} (FT)	3	$16,700,000–$51,800,000	$19,100,000–$59,200,000
Asparagus	2.4×10^{-9}	3.1×10^{-9} (FT)	<1	Not Identified	Not Identified
Bananas	1.2×10^{-6}	6.6×10^{-9} (MN)	1	$2,000,000–$5,000,000	$8,700,000–$21,600,000
Barley	3.3×10^{-7}	2.2×10^{-10} (MT)	<1	$330,000–$1,900,000	$420,000,000–$2,400,000,000
Dry Beans[1]	2.5×10^{-5}	1.3×10^{-8} (M)	<1	$500,000–$1,600,000	$28,000,000–$89,600,000
Beans, Lima[2]	2.4×10^{-6}			$500,000	Not Available
Broccoli	1.3×10^{-5}	2.4×10^{-8} (M)	<1	Negligible	Not Available
Brussels Sprouts	3.8×10^{-7}	3.3×10^{-9} (MT)	<1	Negligible	Not Available
Cabbage	1.2×10^{-6}	5.3×10^{-9} (MT)	1	Negligible	Not Available
Cantaloupes[3]	3.4×10^{-7}	8.7×10^{-9} (MT)	<1	$980,000–$4,900,000	$24,300,000
Casaba melons	5.7×10^{-9}	See Cantaloupes		See Cantaloupes	See Cantaloupes
Cauliflower	2.7×10^{-7}	1.1×10^{-8} (MT)	<1	Negligible	Not Available
Corn, field	7.2×10^{-6}	1.3×10^{-6} (MT)	<1	$1,000,000–$1,500,000	$215,400,000–$323,000,000
Corn, sweet and pop	2.7×10^{-7}	2.9×10^{-8} (M)	<1	$2,100,000–$8,600,000	$21,200,000–$86,600,000
Cotton	6.4×10^{-6}	2.2×10^{-10} (MT)	<1	$27,200,000	$34,600,000,000
Crabapples/Quince	6.1×10^{-7}	4.4×10^{-10} (FT)	<1	Not Identified	Not Identified
Cranberries	5.2×10^{-9}	4.9×10^{-9} (FT)	<1	$70,000	$49,000,000
Crenshaw melons	1.0×10^{-10}	See Cantaloupes		See Cantaloupes	See Cantaloupes
Cucumbers	9.2×10^{-7}	3.4×10^{-8} (M)	<1	$1,400,000–$6,100,000	$12,400,000–$54,000,000
Eggplant	2.5×10^{-6}	2.1×10^{-9} (MT)	<1	Not Identified	Not Identified
Endive	3.2×10^{-8}	3.1×10^{-8} (FT)	<1	Not Identified	Not Identified
Fennel	9.6×10^{-10}	4.4×10^{-10} (FT)	<1	Not Identified	Not Identified
Figs:					
Caprifigs	Non-Food Use	Non-Food Use		Non-Food Use	Non-Food Use
Kadota[4]	1.5×10^{-9}	$<1.0 \times 10^{-10}$	<1	Not Identified	Not Identified
Grapes	9.0×10^{-7}	7.2×10^{-9} (MN)	1	$1,800,000–$17,500,000	$72,000,000–$700,000,000
Honeydews	1.4×10^{-7}	See Cantaloupes		See Cantaloupes	See Cantaloupes
Kale	7.1×10^{-7}	1.0×10^{-7} (FT)	1	$2,100,000–$5,040,000	$5,880,000–$14,100,000
Kohlrabi	1.3×10^{-8}	1.1×10^{-10} (MT)	<1	Not Identified	Not Identified
Lettuce:					
Head		2.4×10^{-8} (M)	<1	$34,800,000–$177,500,000.	$406,000,000–$2,071,000,000
Leaf		1.4×10^{-7} (FT)	2	$5,200,000–$26,500,000	$10,400,000–$53,000,000
Oats	5.8×10^{-6}	3.3×10^{-10} (M)	<1	$3,800,000–$25,000,000	$3,200,000,000–$21,200,000,000
Onions	4.7×10^{-7}	2.6×10^{-8} (M)	<1	$4,200,000–$5,500,000	$50,300,000–$65,800,000
Papayas	1.8×10^{-7}	2.5×10^{-8} (FT)	<1	$240,000–$7,860,000	$1,300,000–$44,000,000
Peanuts	1.6×10^{-8}	1.9×10^{-9} (MT)	<1	$9,100,000	-$2,500,000,000
Pears	1.5×10^{-6}	1.7×10^{-8} (FT)	<1	$300,000	$5,600,000
Pecans	4.0×10^{-10}	$<1.0 \times 10^{-10}$ (FT)	<1	Not Identified	Not Identified
Peppers	3.4×10^{-6}	9.2×10^{-9} (MT)	<1	$80,000,000–$85,000,000	$2,400,000,000–$2,600,000,000
Pineapples	$<1.0 \times 10^{-10}$	Seed-Piece Treatment		Not Identified	Not Identified
Potatoes	1.7×10^{-6}	2.1×10^{-7} (M)	2	$40,400,000	$55,500,000
Pumpkins	1.1×10^{-8}	4.4×10^{-10} (MT)	<1	$139,000–$706,000	$144,100,000–$732,100,000
Rye	3.5×10^{-9}	$<1.0 \times 10^{-10}$ (MT)	<1	$10,000–$60,000	$28,000,000–$168,000,000
Squash	3.4×10^{-7}	2.2×10^{-8} (MT)	<1	$271,000–$810,000	$4,400,000–$13,100,000
Sugar beets	3.7×10^{-7}	3.9×10^{-8} (FT)	<1	Not Identified	Not Identified
Tomatoes	1.6×10^{-5}	2.7×10^{-7} (M)	3	$32,300,000–$45,000,000	$129,200,000–$180,000,000
Watermelons	1.9×10^{-6}	1.1×10^{-9} (MT)	<1	See Cantaloupes	See Cantaloupes

TABLE 1.—SUMMARY OF UPPER-BOUND LIFETIME CARCINOGENIC RISK, PERCENT RfD OCCUPIED, AND BENEFITS ESTIMATES.—Continued

Crop	PD 2/3 Risk Estimates	PD 4 Risk Estimates	PD 4 Percent RfD Range Occupied	PD 4 Benefits Range	Cost-Effectiveness
Wheat	1.1×10^{-7}	1.9×10^{-8} (MT)	<1	$1,663,000–$10,606,000	$245,100,000–$1,500,000,000
Meat (red)	1.8×10^{-7}	1.9×10^{-8} (M)	<1		
Milk (national)	5.6×10^{-7}	2.0×10^{-6} (M)	<1		
Subtotal		1.6×10^{-6}	approx . 47	$268,000,000–$564,950,000.	
Uses to be Cancelled					
Apricots	6.7×10^{-6}	4.7×10^{-7} (FT)	5	Not Identified	Not Identified
Celery	1.8×10^{-5}	8.7×10^{-7} (F)	10	$1,300,000–$3,400,000	$700,000–$1,800,000
Carrots	1.9×10^{-5}	3.9×10^{-7} (FT)	4	$1,200,000	$871,000
Collards	1.3×10^{-5}	1.3×10^{-6} (FT)	14	$5,700,000–$13,680,000	$1,200,000–$2,900,000
Mustard greens	1.7×10^{-5}	2.1×10^{-6} (FT)	24	$4,050,000–$9,720,000	$540,000–$1,300,000
Nectarines	1.0×10^{-6}	7.7×10^{-8} (FT)	1	$10,000	$36,000
Peaches	4.2×10^{-5}	2.6×10^{-6} (FT)	30	$10,000	$1,000
Rhubarb	6.5×10^{-7}	2.8×10^{-7} (FT)	3	Not Identified	Not Identified
Spinach	1.5×10^{-5}	2.1×10^{-6} (FT)	24	$5,000,000–$27,500,000	$667,000–$3,670,000
Succulent Beans[1]		3.7×10^{-6} (FT)	42	$1,300,000–$1,400,000	$99,000–$106,000
Turnips	1.7×10^{-5}	2.1×10^{-6} (FT)	24	$3,150,000–$7,560,000	$420,000–$1,000,000
Total	3.0×10^{-4}	1.8×10^{-5}	approx . 228	$290,300,000–$629,400,000.	

[1]PD 2/3 Risk Estimate includes both dry and succulent beans.

[2]Lima beans are a subset of dry beans and succulent beans (i.e., there are both dry lima beans and succulent lima beans). In the PD 4, a risk estimate for lima beans was Not identified. Rather, beans were classified as dry or succulent.

[3]PD 4 risk and percent-RfD estimates include cantaloupes, casaba, crenshaw, and honeydew; the benefits estimate and cost-effectiveness coefficients include cantaloupe, casaba, crenshaw, honeydew, and watermelons.

[4]In September 1989, the EBDC technical registrants voluntarily cancelled the fig food-use (i.e., kadota figs), leaving caprifigs as a registered use. In the PD 2/3, kadota figs were inadvertently omitted from the dietary risk analysis.

[5]Key: The type of data used in estimating dietary exposure are indicated in parentheses. FT = field trial data; M = market basket data; MT = market basket data translated; and MN = limited monitoring data. See Unit III for a more detailed description of the data.

The type of data used in estimating exposure are indicated in parentheses. "FT" means that the residue estimate is based on field trial data which result from use of the EBDC at maximum application rates, minimum preharvest intervals, and at least the typical number of applications that are typically applied as long as they are within the number of applications allowed on the label. "M" means that the residue estimate is derived from the market basket data which were generated by the EBDC/ETU Task Force. "MT" indicates that the residue estimate was translated from the market basket data. Finally, "MN" means that the residue data were derived from the limited monitoring data which were submitted to the Agency in lieu of banana and grape market basket data.

C. Developmental Toxicity

In the PD 2/3, developmental risk from dietary exposure to ETU was estimated by comparison of maximum exposure estimates for each EBDC to the developmental no-observable-adverse-effect level (NOAEL) (see Unit II). The estimated average margins-of-exposure (MOE) ranged from 770 for maneb to 4,985 for mancozeb; these are considered adequate. For this Final Determination, the dietary exposure estimates decreased; thus, the MOEs would increase. Therefore, the developmental toxicity risk analysis was not repeated.

D. Thyroid Effects

Thyroid effects are assessed using the ETU reference dose (RfD) which was derived from a 90–day rat study; see Unit II.C. for a description of this study. The ETU RfD is compared to the anticipated residues (which are obtained through DRES) to estimate the percent of RfD occupied (i.e., % RfD) for each of the 56 crops.

EPA estimated the percent RfD occupied for the overall U.S. population, the infants subgroup, and the children subgroup. The percent RfD occupied estimates for the infants and children subgroups are discussed in Unit VII.A. The percent RfD occupied estimates for the overall U.S. population are listed in Table 1 in Unit III.B. of this Notice.

E. Comments and Response: General (Refs. 6 and 36)

1. *Comment.* One commenter questioned the Agency's proposal to cancel EBDC use on potatoes while retaining use on grapes and onions. The commenter stated that it appears inconsistent to cancel a root crop like potatoes where there is no direct spraying of the edible portion (and no translocation of the EBDCs into the plant or tubers) and to retain grapes, where there is direct spraying of the fruit. Further, the commenter believes that potatoes, like onions, are unlikely to contain significant EBDC/ETU residues due to the underground development of edible portions and likely washing, peeling, and time in storage.

Response. The proposed cancellation of potatoes was based on a risk/benefit balancing that demonstrated a relatively high estimated risk for potatoes compared to relatively low estimated benefits. When estimating risks from each individual commodity, EPA is concerned with the risk due to ETU, the common degradate of the EBDCs which is carcinogenic. ETU (unlike EBDCs) is transported through the crop and can be measured in all plant parts including potato tubers. There is also the potential for EBDC transfer to the potato tubers from the soil during harvest. The EBDC/ETU residue estimates incorporate available washing, peeling, and other processing information. Finally, even though the ETU residue estimate may be relatively small, the resultant risk estimate for a commodity such as potatoes can be significant because the consumption estimate is relatively high.

2. *Comment.* Several commenters stated that unrealistic assumptions were used by EPA in the exposure estimates and that dietary exposure should be reassessed using realistic estimates of both EBDCs and ETU. Examples of what the commenters suggested were unrealistic assumptions include: using residue data from produce sampled at the farm gate to estimate residues in consumed produce; and for non-detectable residues, assuming that all EBDC-treated crops contain residues equal to the limit of detection. The commenters suggested that more realistic estimates would be based on produce for sale in the marketplace, not on produce as it is taken directly from the plant in the field. The commenter further stated that better data are needed to estimate ETU residues and points out that EPA admits that the current data overstate the dietary risk to consumers.

Response. The Agency acknowledged in the PD 2/3 that the field trial data (reflecting residue levels at the farm gate) were likely to overstate the residue levels in produce as consumed. However, these field trial data (which were corrected for washing, peeling, cooking, and other processing factors) were the best data available at the time of the PD 2/3 for dietary exposure assessment. Because the Agency expected that the available data would overstate the residues in food as consumed, EPA required the EBDC registrants to provide market basket data (i.e., data on foods collected in grocery stores). For this Final Determination, the Agency estimated dietary exposure from the market basket data that were submitted including additional processing factors, as appropriate.

EPA did not assume that all crops treated with EBDCs contain residues equal to the limit-of-detection. For the PD 2/3, the Agency assumed that all non-detectable residue levels were present at one-fourth the limit-of-quantitation (LOQ). EPA believed that this was a reasonable assumption because environmental data, which include pesticide residues, are usually distributed log-normally. A log-normal distribution is one in which the logarithms of the residue estimates are distributed according to the familiar bell-shaped curve. The average of a log-normal distribution is about one-fourth the maximum value. In the PD 4, EPA assumed that non-detectable residues were present at one-half the LOQ. The Agency changed its assumption because one-half of the LOQ, which is based on the assumption that residues are normally distributed, is more commonly used throughout the scientific community and within EPA for other chemicals. Also, one-half LOQ is a more conservative assumption.

Finally, ETU residues are not the only concern with the EBDC fungicides. While it is true that the Agency needed better data to estimate ETU residues, the Agency also needed better data to estimate EBDC residues because EBDC residues can convert to ETU during cooking or other processing and in the body. Dietary risks due to consumption of ETU residues are added to the risks due to the conversion of EBDCs to ETU. Thus, better data on the amount of both EBDCs and ETU were needed. The EBDC/ETU market basket study was required for this purpose.

3. *Comment.* One commenter noted that market basket surveys do not provide any indication of whether, when, or at what rate EBDCs were applied or when the crop was harvested; thus, the required market basket study cannot indicate if reduced rates of applications or extended preharvest intervals might eliminate the current residue problem.

Response. The Agency agrees with the commenter. Market basket data do not provide information on the use patterns used during the survey period nor do market basket data shed light on residues resulting from other alternative use patterns. However, market basket data do provide residues from actual (typical) treatment of the surveyed items. For the PD 4, the Agency estimated the typical use pattern used during the year the market basket survey was conducted through NAPIAP data, contacts with agricultural specialists, and comments submitted to the Agency in response to the PD 2/3.

4. *Comment.* One commenter stated that relying on market basket surveys for estimating dietary exposure is not protective of human health unless tolerance levels are lowered. Further, without an accurate residue monitoring system, the commenter stated that the Agency must assume that residues are at tolerance levels because this is the legally enforceable level. Even if the residue levels later found exceeded the assumed market basket survey level, the Agency would have no legal mechanism to protect the public health. Thus, if the Agency prefers to regulate at some market basket level, then the tolerance level should be lowered accordingly.

Response. EPA disagrees with the commenter. Tolerances are set at the maximum level of pesticide likely to be found on foods treated at the maximum use pattern on the label. Residues are not likely to be found routinely at this level for several reasons. First, average residues from use at the maximum rate and minimum preharvest intervals are not likely to be at the tolerance level because the tolerance level should be set at an upper limit of the residues being found in field trials. Second, not all crops are treated with the maximum use pattern on the label or harvested at the minimum preharvest interval; some are not treated at all. Third, degradation or removal of the residue may occur during storage, commercial processing, or as a result of consumer practices, such as washing, peeling, and cooking. In addition, a consumer is not likely to consume food items always containing tolerance level residues. Over a lifetime, the residue levels actually consumed should approach the average level of residues found in the United States. Nonetheless, the Agency will be lowering tolerances, where appropriate, as a result of the data received in response to the PD 2/3. Finally, FDA will continue to monitor foods for pesticide residues and take appropriate action for residues exceeding tolerances. If average residues from FDA monitoring increase significantly such that there is likely to be a health hazard, the Agency will take appropriate action.

5. *Comment.* One commenter stated that the Agency should rely on the basic data base previously provided by the primary registrants to support all crops voluntarily cancelled by the technical registrants and that the voluntary cancellation of a few uses for a pesticide active ingredient should not invalidate the total data base.

Response. The Agency agrees with the commenter. Voluntary cancellations by the technical registrants do not invalidate previously submitted data. However, the previously submitted data, while they may be the best available data and may have been used in the dietary exposure assessment, may not meet the requirements for new or continued registration or for the purpose of ensuring that tolerances are established at the correct level. Thus, additional data may be required.

6. *Comment.* One commenter stated that the method for handling residue levels in apples below the LOQ requires refinement. Currently, the Agency uses one-half the LOQ as a residue estimate when residues appear non-detectable. The commenter believes most residues in apples are much below one-half the LOQ and that using that value overestimates the residue level. An appropriate residue level to be used for nondetectable residues would be zero because even very small residue levels

may have significant impacts on the risk assessment and EBDCs are non-systemic.

Response. EPA disagrees that zero would be an appropriate residue level for apples where such residues are non-detectable. First, a non-detectable residue is not necessarily zero as it is analytically impossible to measure zero due to the limits of the analytical methodology and instrumentation used to measure EBDCs and ETU. So, to be protective of human health, EPA must assume that residues are present at some level below the LOQ. For the PD 4, EPA assumed that non-detectable residues are present at one-half the LOQ. The choice of this level is discussed in Unit III.E.2. Secondly, even though EBDCs are relatively nonsystemic, residues may still be present at harvest.

7. *Comment.* One commenter pointed out that a number of key crops (i.e., carrots, leaf lettuce, peaches, spinach, and succulent beans) which should have been included in the market basket survey to more accurately determine dietary exposure were not included in the survey. Not only do these crops represent important registration needs, but data from these crops would be translated to other crops including celery, collards, endive, fennel, kale, lima beans, mustard greens, rhubarb, snap beans, and turnips to support continued registration.

Response. Even though carrots, leaf lettuce, peaches, spinach, and succulent beans were specified in the March 10, 1989 EBDC Data Call-In, the technical registrants chose not to include these crops in the required market basket survey for these commodities. Further, no other person or group chose to submit such data either. The default data to be used in the absence of the required market basket survey data are the same field trial data that were used for the dietary exposure analysis in the PD 2/3. In the absence of the required market basket survey data and other data which could have been provided by interested parties, the existing field trial data are the best available data for the dietary exposure analysis for these crops.

8. *Comments received on risk reduction measures and methods.* A number of commenters stated that crops are often washed before being sent to market and some suggested mandating a more thorough washing procedure to reduce EBDC residues and risk, rather than banning the use of EBDCs.

Response. EPA has adjusted the residue estimates for washing prior to consumption. Commercial processing studies include the effects of washing. Studies have indicated that 78 percent of consumers wash their produce prior to consumption (Ref. 29). The Agency, on numerous occasions, has recommended thorough washing of fruit and vegetables to help remove pesticide residues. Because the label might not be seen by the persons responsible for washing, the Agency does not believe that a label requirement to require washing after harvest would be appropriate.

9. *Comment.* Several commenters suggested that preharvest intervals be lengthened, application rates reduced, and that the use of Integrated Pest Management (IPM) be mandated. Further, a commenter suggested that labels be changed so that no detectable residues result in potatoes and other vegetables.

Response. Longer preharvest intervals and reduced application rates are likely to reduce residue levels to some degree; however, such measures might reduce the efficacy of the EBDC fungicides in some cases. Without crop residue data demonstrating the amount of residue reduction and the effect on the efficacy of the fungicide, the Agency cannot fully evaluate these options and estimate potential residue reduction. Further, without residue data, the Agency cannot predict what label changes would be required to result in non-detectable residues. Where it had information on which to base such considerations, the Agency did consider potential altered use patterns as options short of cancellation, along with a requirement that data be submitted to better quantify the amount of risk reduction that could be attained and its effect on plant disease control. Further, for many crops, the technical registrants have proposed use patterns that would result in lower residues. For a number of crops, altered use patterns are being required to reduce dietary risk.

10. *Comment.* A food company suggests postponing cancellation and delaying revocation of tolerances for the southern leafy greens (i.e., collards, kale, mustard greens, and turnip greens) so current uses may be continued under FIFRA section 24(c). These actions are needed so research work currently under way to find substitute methods to control disease can be completed without severe economic consequences during the transition. The company suggests that 3 years should be sufficient to allow for development of alternative control measures.

Response. The Agency believes that it is inappropriate to postpone cancellation of the leafy greens and to delay tolerance revocations to allow use for research purposes because of the estimated dietary risks that would be associated with consumption of EBDC-treated leafy greens. Further, under FIFRA section 24(c), such registrations may not be issued for uses where the registration has been cancelled. Any existing 24(c) registrations for leafy greens would be cancelled along with the other EBDC registrations for such commodities. For research purposes, an experimental use permit may be sought under FIFRA section 5. Also, petitions may be filed with the Agency under 40 CFR 104.130, subpart D if prerequisite requirements are met.

11. *Comment.* One commenter expects levels of maneb residues to be present following the use of Bravo® C/M, which contains chlorothalonil and maneb, to be much lower than would be expected from maneb used alone on all crops for which Bravo® C/M is registered. No residue data were provided to show actual residues of maneb or ETU from the use of Bravo® C/M.

Response. The commenter did not provide data to determine the maneb and ETU residue levels in produce treated with Bravo® C/M. The Agency believes that when maneb is applied at lower rates, lower residue levels will likely result, but the Agency is unable to extrapolate to the levels expected from the use of Bravo® C/M without data.

F. Crop-Specific Comments and Response

1. *Comment on apples.* Several commenters stated that they had participated in a residue study organized by the New England Fruit Growers Council for the Environment, with sampling and analysis being done by the Connecticut Agricultural Experiment Station. Residues in apples were many times below tolerance and the investigators did not find a strong linear correlation between preharvest interval and residue level. The commenters noted that the results are consistent with those of the market basket survey being conducted by the EBDC registrants.

Response. EPA has reviewed the study provided by the New England Fruit Growers Council; the Agency's detailed comments are available. The results of the New England study were found to be consistent with the IAI study (which was used in lieu of the market basket data) reflecting EBDC applications at reduced rates and increased preharvest intervals. The relationship between the preharvest interval and residue level (at the same application rate) was logarithmic as opposed to linear.

2. *Comment on risk reduction for apples.* Many commenters discussed risk reduction measures for apples and possible mechanisms to achieve lower residues. A number of northeastern apple growers stated that EBDCs are needed most early in the season (up to petal fall). The commenters stated that the period from green tip until petal fall is the most critical (usually from early May to mid-June), although the users would prefer to have EBDCs to use through second cover. Harvest is usually in September and October. Further, commenters have indicated that early season use (up to petal fall) should not result in residues at harvest because the residues should degrade by harvest.

Specific suggestions to reduce residues include: Use EBDCs on apples in an IPM program; reduce the tolerance to 3 ppm; require a longer interval between applications; reduce the label rate for summer sprays; lengthen the preharvest interval from 30 days to 60 days or limit use to before July 1; allow less EBDCs to be applied per year and limit the total number of applications per year; and/or require washing of treated apples after harvest.

Commenters noted that many states recommend one-half the label rate as part of an IPM program; thus, lower rates are already in practice and can be assumed to be efficacious. Regional data indicate that EBDCs are regularly used at rates that are at least one-third less than the maximum label rates. The 1989 use survey by IAI showed a large distribution of preharvest intervals in excess of 70 days more than the minimum preharvest interval given on the EBDC labels.

Apples are washed and usually peeled during the processing operation. One commenter referred to a study demonstrating reductions in residues from washing before commercial processing. Other commenters stated that EBDC residues are on the surface only and do not enter the tissue of the apple. They weather, degrade, are washed off, or are removed by peeling. Several commenters stated that EBDCs work well at one-half the normal rate in combination with benomyl or one of the sterol inhibitors.

Response. The EBDC/ETU registrants and IAI have cooperated in investigating a new use pattern for apples using lower application rates and extended preharvest intervals. The IAI data showed low levels of EBDCs and ETU from treatment through bloom; data through second cover were also provided. Washing of apples was considered in the Agency's dietary exposure estimates for the PD 2/3 and was also considered in the PD 4 exposure estimates. Washing and peeling during commercial processing is incorporated into commercial processing factors which were used in both the PD 2/3 and PD 4.

3. *Comments on bananas.* One commenter stated that his organization has quality assurance programs to monitor EBDC levels on unpeeled bananas. Analyses are received on a quarterly basis and the results to date are well below the 4 ppm tolerance. The portion of the banana that is eaten is also tested and no detectable residues have been found. The International Banana Association (IBA) states that banana companies using independent laboratories normally monitor their products to ensure that pesticides residues are negligible or well within tolerances. They point out that bananas are peeled before consumption and that EBDC residues remain on the peel. Fruit with a ruptured peel is removed during prepack quality inspection. Residue tests conducted by IBA member companies have consistently demonstrated the near absence of EBDC derived residues in the edible portion of bananas. The IBA member data were not included in the comment.

The Hawaii Department of Agriculture provided growing information and a summary of residue data for Hawaiian grown bananas. The commenter suggests the following risk reduction measures: establish a 48-hour preharvest interval for bananas; prohibit post-harvest applications of EBDCs; and require that bananas treated with EBDCs be washed after harvest.

Response. A limited monitoring study of imported bananas was done by the EBDC/ETU Task Force (Ref. 20). Banana pulp (the edible portion) was analyzed for EBDC and ETU. Residue levels were reported to be non-detectable in all but one sample. The data from this limited monitoring study were used for the dietary exposure analysis for the PD 4.

Data on Hawaiian bananas are not used for the dietary exposure analysis because Hawaiian bananas represent a very small portion of the bananas available for consumption in the United States. However, the Hawaiian data are important for the continued United States registration of EBDCs on bananas and will be utilized in reassessing the tolerance for bananas.

4. *Comments on carrots.* One commenter suggested the use of EBDCs with IPM programs. Suggested label changes for carrots include: (a) Use lowest rates at the beginning of the spray program, later in season use higher rates to maintain control; and (b) Extend preharvest interval to 21 days.

Another commenter stated that most residues on carrots would be on the above-ground crown of the carrot root. An extended preharvest interval would give time for residues to decline before harvest. Carrots grown for processing are crowned in the field, and only the below ground roots are harvested. At the processing plant the carrots are washed several times, peeled, and washed again before final processing. An extended preharvest interval would also reduce residues in processed carrots.

Response. The residue level of EBDCs, and non-systemic pesticides in general, is most strongly influenced by the application rates used closest to harvest. Thus, using lower rates early in the season and higher rates late in the season would not be expected to reduce residue levels significantly. Residue decline data would be needed to support a longer preharvest interval. In addition, extending the preharvest interval in one growing region may not be acceptable in terms of efficacious disease control in other carrot growing regions.

5. *Comments on hybrid corn production.* A hybrid seed corn producer stated that the risk to consumers from seed corn treated with EBDC fungicides would be negligible. The acreage of seed corn actually treated annually with fungicides is quite small.

Response. In addition to hybrid seed corn production, the Agency must also consider the use on field corn not grown for seed. The EBDC use on field corn is quite small. This was factored into the dietary risk assessment by multiplying the residue and consumption estimates by percent of crop treated.

6. *Comment on cotton.* A cotton grower was unaware of any data that have shown an adverse dietary effect from the use of EBDCs on cotton. The label specifies that EBDCs should not be applied after cotton bolls open; thus, none of the pesticide comes in direct contact with the seed from which cottonseed oil is extracted. EBDCs are applied at 1.6 pounds of active ingredient per acre (lb. a.i./A), 3 applications at 12 to 15 day intervals, after rust spores infect the cotton plants and before boll opening.

Response. Residue levels reported in cottonseed are low, reflecting the early season use. The estimated risk from the use of EBDCs on cotton includes that low level residue and consumption of cottonseed oil and the percent of crop treated.

7. *Comment on crops grown in Georgia.* One commenter is concerned about leafy greens, peppers, and other crops grown in Georgia. The University

of Georgia Department of Horticulture points out that broccoli, cabbage, cauliflower, collards, kale, mustard, and turnips are all in the genus Brassica of the botanical family Cruciferae. The commenter requests that the Agency translate market basket survey data from broccoli to other Brassica vegetables.

Another commenter states that using field trial data and ignoring normal processing methods overstates residue levels on leafy greens. EBDCs are easily diluted by water, with an ordinary rainfall capable of removing the major portion of the residue. Thorough washings are part of canning or freezing processing methods. FDA studies have shown that 89 percent of all produce sampled contained no detectable EBDC residues, and 98 to 99 percent of residues detected were well below established tolerance levels. No one is expected to eat leafy greens in the field. Therefore, testing for residues should give full consideration to the product after it has been handled, not in the unrealistic setting of sample collection in the field.

Response. During the development of the market-basket data requirement, the Agency considered the fact that broccoli, cabbage, cauliflower, collards, kale, mustard, and turnips are all in the same genus and botanical family. EPA is concerned that the exposed surface area for collards, kale, mustard, and turnips would be more likely to lead to higher residues than the exposed surface area of broccoli, cabbage, and cauliflower. Several registrants have noted (in their comments on the current crop grouping scheme) that this occurs. Thus, the Agency believed that it was necessary to collect market basket data for a higher surface area crop (i.e., spinach). Spinach was chosen based on its grouping in 40 CFR 180.34(e). Washing factors (reflecting reduction of residues on washing) and processing factors (cooking or canning) were used in the dietary exposure assessment for the PD 2/3 and are used in the PD 4.

The statistics on the FDA monitoring data quoted by the commenter apply to all chemical/crop combinations monitored and not specifically to EBDCs and ETU on leafy greens. In fact, FDA has found numerous over tolerance residues of EBDCs on a number of leafy greens including mustard greens, spinach, and turnip greens over the past 12 years. Additional leafy green monitoring samples had detectable residues, but not exceeding the tolerance.

8. *Comments on green peppers.* One commenter suggested that the tolerance for green peppers be reduced from 7 ppm to a lower number consistent with actual residues found in the market basket survey. The commenter also suggested instituting a 2–day preharvest interval and requiring washing of peppers prior to packing.

Another commenter stated that there are no alternatives for eggplant and peppers. Increasing the preharvest intervals from 5 days to 14, 21, or even 28 days was suggested.

Response. Tolerances are set at the maximum level likely to be found as a result of the most extreme use pattern on the label and cannot be set at a level found in the market basket survey because tolerance exceeding residues could regularly occur. Residue decline data would be needed to fully evaluate the suggested changes in preharvest intervals. Some decline data are available, but were not used because pepper residue estimates were based on the market basket survey data rather than being extrapolated from field trial data.

The Agency does not believe that a label requirement requiring washing after harvest would be appropriate because it would be difficult to enforce. EPA has recommended thorough washing of fruits and vegetables to remove pesticide residues. Nonetheless, EPA believes that most crops are washed prior to consumption and the residue estimates (except for crops such as onions and bananas which are peeled rather than washed) have been adjusted by including a washing factor where appropriate. Finally, the Agency recognizes that there are no registered, efficacious alternatives to EBDCs for eggplants and green peppers.

9. *Comments on greens.* Several commenters questioned the source of average residue estimates for collards, kale, mustard greens, spinach, and turnip tops found in Table II-7a of the Technical Support Document (Ref. 8). The average residue levels indicated were 3 to 5 times higher than the current tolerance levels. The commenters had not seen these residue levels reported elsewhere, nor experienced those high levels in their own testing programs. The results of the commenters testing programs were not submitted.

Response. The source of the residue estimates used in PD 2/3 was data from field trials conducted by the registrants as a requirement of continued registration. The average residues in those field studies exceeded the current tolerances. This was not surprising as FDA has found (in their surveillance monitoring program) tolerance-exceeding EBDC residues on several leafy greens numerous times in the past 12 years. Tolerance-exceeding residues of EBDCs have been reported in the open literature. Studies submitted by commenters also showed over tolerance residues. The residue estimates in the PD 2/3 were corrected for the effects of washing.

10. *Comments on greens.* A greens grower in the Southeast states that there are no efficacious alternatives to EBDCs for greens (i.e., collards, kale, mustard greens, and turnip greens). One commenter indicated that even though the label recommends 1.2 to 1.6 lb. a.i./A, the standard practice in the Southeast is 1.0 lb. a.i./A; however, another commenter in the Southeast submitted a study that indicated that the rate of 1.6 lb. a.i./A was required for efficacy. Further, one commenter stated that all greens are thoroughly washed before being cooked; washing reduces residues to negligible levels. Finally, using lower rates and spraying less frequently than labelled saves money.

Response. The Agency realizes that there are no registered, efficacious alternative fungicides for leafy greens. Data were not submitted to the Agency at the 1.0 lb. a.i./A rate, only at the 1.6 lb. a.i./A rate and a 0.8 lb. a.i./A rate. An evaluation of preharvest interval on disease control was also included. The data indicated that the preharvest interval should not exceed 10 days. In addition, the 0.8 lb. a.i./A rate may not be effective for disease control, especially for fall cuttings. However, no data were available for the Agency to assess the efficacy of the 1.0 lb. a.i./A rate.

11. *Comments on onions.* The American Dehydrated Onion and Garlic Association submitted actual use information for dry bulb onions used for dehydration. They noted that EPA assumed applications at 2.4 lb. a.i./A, 6 to 10 applications per season, and a preharvest interval of 7 days. Their members used 2.4 lb. a.i./A, 1 to 3 applications per season, with a preharvest interval of 30 to 45 days. If Ridomil® MZ–58 (metalaxyl + mancozeb) were used, the rate used was only 1.0 lb. a.i./A. The Ridomil® label allows only four applications per year. Ridomil® MZ58 is most often used.

This commenter also submitted information on planting, growing, and harvesting practices for dry bulb onions destined for dehydration. One commenter stated that 60 to 70 percent of the dry bulb onions grown in California are grown under contract for drying.

The National Onion Association noted that the market basket survey results do not reflect further residue reductions that occur in typical

consumer food preparation practices. They state that EBDCs are not systemic and do not penetrate into the vegetable or fruit. Any remaining residue after harvest can be washed, rinsed, or peeled off. The outside peel of an onion is never eaten.

Several commenters stated that there was possibly a naturally occurring component of dry bulb onions (carbon disulfide) that might be interfering with the EBDC analysis in the market basket survey. Data were submitted for apparent EBDC residues in untreated onions. The apparent EBDC in untreated onions ranged from 0.05 to 0.36 ppm. The commenters requested that the Agency subtract the average residue found on untreated dry bulb onions from the result found in the market basket survey.

Response. Dietary exposure estimates for onions are now based on the EBDC/ETU market basket survey with corrections for washing, peeling, and cooking. The market basket survey results have been corrected for the apparent carbon disulfide interference in the EBDC analysis. The market basket survey results reflect the typical use pattern.

12. *Comments on papayas.* Several commenters stated that the actual risk to papaya consumers is much less than that estimated by EPA because of conservative application practices currently employed or proposed to be employed by the papaya industry and the reduction of any remaining EBDC residues during commercial handling, storage, transportation, and consumer handling. Under the Hawaiian Fruits and Vegetable Act, fresh commodities exported to the continental United States must be treated with an approved quarantine treatment prior to shipment. In Hawaii, two quarantine treatment systems (double hot water dip and vapor heat treatments) are used commercially. A study examining reduction of residues during commercial handling, storage and transportation has been submitted (Ref. 4).

The commenters stated that mancozeb and maneb are not applied at maximum label rates. Only the minimum number of applications that result in economic benefit are used. Further, papayas are harvested later than the minimum time allowed on the label. They also stated that EBDC and ETU residues at harvest are substantially lower than those shown in field trial data developed to support tolerances.

Information was provided about the growing of papayas and specific information about EBDC treatments. Fruit are sprayed frequently beginning at fruit set which is about 6 to 10 weeks after planting. The fruit and flower column must be sprayed every 14 days for routine prevention. A given fruit generally does not receive more than 13 biweekly mancozeb or maneb sprays by the time of harvest. Another commenter stated that papayas are sprayed frequently beginning at fruit set (6 to 10 months after planting), every 14 days during dry conditions, and every 7 days during rainy conditions.

The commenters offer the following suggestions for risk reductions: Reduce the papaya tolerance from 10 to 5 ppm; increase the application interval from 7 to 14 days; impose a 2–day preharvest interval; require washing of fruit prior to packing (this is already required by the Hawaiian Fruits and Vegetables Act); and prohibit feeding of treated fruit to livestock.

Response. The papaya growers' data have been considered in the Agency's dietary exposure analysis (Ref. 4). The papaya tolerance cannot be reduced under the current use pattern because tolerance-exceeding residues have been reported in field studies reflecting treatment at the maximum use pattern. The maximum rate is being reduced to keep residues within tolerances. The available residue data are for application intervals of about 14 days. A minimum interval of 14 days is being required. A 2–day preharvest interval would not reduce risk because the residue levels reported in field studies were highest 2 days after harvest. Thus, the minimum preharvest interval will remain at zero days. Papayas are not considered a major animal feed, so a label restriction against feeding treated fruit to livestock is not considered necessary. The Agency does not believe that a label requirement requiring growers to wash papayas after harvest is appropriate because it would be difficult to enforce. Nonetheless, EPA believes that most crops are washed prior to consumption and thus the residue estimates have been adjusted by including a washing factor.

13. *Comments on pears.* The mancozeb label allows 24 to 30 lb. product/acre/year but only 12 to 18 lb. product/acre/year is reportedly used in California based on the required California pesticide use reporting. Mancozeb is first applied to pears after bloom through the small red pear stage (April to May); harvest is the last week in July. Therefore, a minimum of 30 to 45 days pass between the last application and the first harvest; thus, the preharvest interval could be extended. Also, EBDCs work well in IPM programs. In the Northeast, mancozeb is needed on pears through petal fall. One commenter stated that early sprays will leave limited residues at harvest.

Response. New field trial data reflecting a modified use pattern (i.e., longer preharvest interval) have been submitted for apples. These data have been translated to pears for the dietary risk assessment and result in a lower risk than was previously estimated. No data were submitted to show the change in residues from the California use pattern on pears. Pears are grown in California; Oregon/Washington; and New York/Michigan. Information was not provided for Oregon/Washington or New York/Michigan.

14. *Comments on potatoes.* Several commenters suggested the use of IPM on potatoes and stated that fewer treatments of EBDCs are used with IPM programs. For potatoes in Wisconsin, one to three fewer treatments are needed.

Suggested label changes for potatoes include: (a) Use lowest application rates at the beginning of the spray program and higher rates later in the growing season to maintain efficacious disease control; (b) Kill the vines 14 days before harvest to reduce a source of fungal inoculum; and (c) Extend the preharvest interval to 14 days as most growers already observe a 14–day preharvest interval. The 0-day preharvest interval invites contamination of tubers with fungicide residues. Chlorothalonil could be used with a 7–day preharvest interval.

The Maine Department of Agriculture Food, and Rural Resources states that seed potatoes in Maine are grown on one/third of Maine acreage. Dietary exposure to EBDC residues on seed potatoes is negligible because virtually all seed potatoes are used for purposes other than consumption. They request that EPA exclude seed potato acreage when estimating risk for EBDCs. They also suggest adding a preharvest interval for potatoes.

Response. The residue level is most strongly influenced by the application rates used closest to harvest. Thus, using lower rates early in the season would not be expected to reduce residue levels significantly. Nonetheless, EPA is requiring changes in the potato use pattern, including extending the preharvest interval, to reduce the dietary risk. The dietary exposure estimate for potatoes in the PD 4 is based on the market basket data for potatoes; therefore, residue levels in seed potatoes were not considered. The Agency acknowledges that a potato vinekill program is helpful to reduce fungal infection.

15. *Comments on tomatoes.* A Federal marketing order requires all Florida tomatoes to be washed prior to entering primary channels-of-trade and inspected by the Federal-State Inspection Service. The commenter states that after picking (90 percent of Florida tomatoes are picked at the mature green stage), tomatoes are placed in ripening rooms for 3 to 5 days and then transported to market. When the tomatoes are transported, they are still not ripe and require several more days at room temperature to fully ripen prior to consumption. Any residues not washed off in the packing process have this additional time to decompose.

Tomato growers in the Southeast stated that farmers stop the application of EBDCs once harvesting begins in order to adhere to the present 5–day preharvest interval. Tomatoes are washed before packing so that actual residue levels are quite low.

The Florida Fruit and Vegetable Association and the Florida Department of Agriculture and Consumer Services submitted a study on degradation of EBDCs in the channels-of-trade. The California tomato growers provided use information for tomatoes.

Response. The Florida degradation study of EBDCs in the channels-of-trade was not used in the PD 4 for tomatoes because the EBDC/ETU market basket survey collected tomatoes in grocery stores, and thus already reflected the reductions measured in the Florida Study. The California use information and the Florida degradation study both corroborate the results of the market basket survey on fresh tomatoes.

G. Other Studies Submitted: Comment and Response

1. *Comment from the Florida Fruit and Vegetable Association.* Florida growers were surveyed on actual use rates, number of applications, and preharvest intervals for a number of crops including cabbage, cucumbers, eggplants, green beans, Irish potatoes, peppers, squash, sweet corn, tomatoes, and watermelons. Descriptions of handling of the commodity after harvest, any processing done, packaging used, and length of time from harvest to sale were also discussed in the comment.

The acreage treated varied from year to year, but the basic rate used per acre, the number of applications, and the preharvest interval remained constant from year to year. Users generally applied less than the label rate and used the label rate only to maintain efficacy. Preharvest intervals are observed and often longer intervals are used, but Florida users do not support longer preharvest intervals on the label unless it is necessary for the continued registration of EBDCs.

Post-harvest practices that would reduce residue levels include: use of directed sprays, water bath to handle product (prevents bruising prior to packing), overhead irrigation prior to harvest to rinse off excess EBDCs, and switching to an alternative fungicide prior to harvest. Most growers use a wash system or hydrocool process with a majority of the vegetable products. Some products are packed in the field, but those that go through a packing house will receive two to three water baths. The only processing done is removing some of the outer leaves and water baths. A post-harvest handling study (i.e., degradation in the channels-of-trade) was also submitted.

Most vegetable products go to market on the day of harvest, and reach the consumer in 3 to 7 days. Fresh vegetables are perishable and must be handled and moved quickly to maintain fresh quality.

Response. Washing is considered in the Agency's dietary exposure analysis. The Florida post-harvest handling study was used to determine EBDC processing factors for carrots and celery. Factors for lettuce and tomatoes could be determined from this study but were not needed because head lettuce and tomatoes were included in the market basket survey. The actual use pattern and post-harvest handling are reflected in the residues of crops included in the market basket survey. The actual use pattern cannot be considered for green beans because of lack of residue decline data; no market basket survey data or field trial data were submitted for green beans reflecting alternative use patterns.

2. *Comment from the Iowa Fruit and Vegetable Growers.* A use survey of Iowa apple, squash, and tomato growers was submitted. Most growers surveyed support longer preharvest intervals to reduce residue levels but not so long as to effectively ban use. Farm practices used to reduce residue levels are spraying the minimum amount of pesticide, using IPM, and washing tomatoes many times before processing. Some growers wash or hydrocool their crop after harvest, and some use mechanical brushes. The length of time from harvest to sale was reported to be 3 days to 6 months for apples, 1 day to 2 weeks for cucurbits, and 1 day to 1 week for tomatoes.

Response. The increase in preharvest interval would be difficult to evaluate without residue decline data. Data are available for a different use pattern for apples and were considered in support of risk reduction measures.

IV. Occupational/Homegardener Exposure and Risk

Part of EPA's basis for initiating a Special Review of the EBDCs was concern that agricultural workers, industrial workers, and homegardeners may be at risk for carcinogenic, developmental, and thyroid effects from exposure to EBDCs and ETU through mixing, loading, and applying EBDC pesticide products to food and non-food crops and conducting field labor in treated areas.

The majority of agricultural uses of the EBDCs (e.g., farming, commercial greenhouse applications, and commercial turf applications) are preharvest. The EBDCs are also used as a seed-piece treatment for potatoes. Because of the many different crops to which EBDC products can be applied, and certain similarities among them, the Agency selected six crops which it believes represent exposure associated with all other crops and types of application. They are apples, grapes, onions, potatoes, sweet corn, and tomatoes. Application methods for EBDCs include ground boom and airblast. EBDCs are also applied to commercial ornamental trees, plants, and shrubs by tractor-mounted power hand-held spray guns.

Homegarden uses of EBDCs include those around the home such as garden, lawn, or tree/shrub applications. Exposure estimates were developed for homegarden application of EBDCs to vegetables, ornamentals, fruit trees, and turf using compressed air hand-held sprayers or hose-end sprayers. Homegarden uses were referred to as homeowner uses in the Preliminary Determination (PD 2/3). The terminology has been updated in the Final Determination (PD 4) for clarity, as homegarden is what the Agency intended in the PD 2/3.

For nabam's industrial uses (i.e., water cooling systems, oil drilling, and paper and sugar mills), there are two types of loading systems: open pour loading and closed loading. Only the water cooling systems (towers) and oil well drilling fluids use an open pour loading system in addition to closed loading systems. The use of nabam in paper and sugar mills employ only closed loading systems.

A. Preliminary Determination

In the PD 2/3, the Agency estimated EBDC exposures using surrogate data bases (i.e., data collected during the use of another pesticide). Mixer/loader and applicator exposures are always dependent on the physical parameters of

application rather than the chemical properties of the pesticide active ingredient. Therefore, mixer/loader and applicator exposure to a pesticide may be estimated using surrogate data.

The initial agricultural worker, industrial worker, and homegardener cancer risks estimated for the EBDC PD 2/3 ranged from 10^{-3} to 10^{-7} (Ref. 8). Occupational risks were estimated assuming that applicators (also potato seed-piece planters and flaggers) wear long-sleeved shirts and long pants, and that mixer/loaders (also the filler and cutter for the treatment of potato seed-pieces) wear long-sleeved shirts, long pants, and chemical-resistant gloves. Protective clothing and equipment specified in the Registration Standards for mancozeb, maneb, metiram, and nabam consists of coveralls, shoes, socks, goggles or a face shield, and chemical-resistant gloves. Also, the use of a chemical-resistant apron during mixing and loading was specified in the Registration Standards. These specifications were factored into the Agency's preliminary analysis. For the PD 2/3 exposure estimates, it was assumed that the use of coveralls by the mixer/loader would reduce exposure by 40 percent (the use of chemical-resistant gloves was already reflected in the original mixer/loader exposure estimates), and that the use of coveralls and chemical-resistant gloves by the applicator would reduce exposure by 65 percent. Most of the occupational carcinogenic risks, which were estimated assuming the use of the coveralls and chemical-resistant gloves, were 10^{-4} or less. Relabelling to require the use of the protective clothing and equipment specified in the Registration Standards was proposed in the PD 2/3. Homegardener exposure estimates were not adjusted for any protective clothing assumptions. Most of the homegardener risks were estimated to be 10^{-6} or less. The occupational and homegardener cancer risks of concern in the PD 2/3 are shown in Table 2 in Unit IV.B. of this Notice.

Using the same protective clothing assumptions listed above, margins-of-exposure (MOEs) were estimated for agricultural workers, industrial workers, and homegardeners who may be exposed to EBDC pesticide products. Developmental MOEs were estimated using daily exposure estimates for acute effects. Thyroid MOEs were estimated using seasonal exposure estimates. The subchronic no-observable-effect level (NOEL) and the chronic lowest-observable-effect level (LOEL) for the thyroid effects MOE calculation is 0.25 mg/kg/day (Ref. 8). The NOEL for the developmental effects MOE calculation is 5 mg/kg/day (Ref. 8). Most MOEs reported in the PD 2/3 were greater than 100. The MOEs of concern in the PD 2/3 are shown in Table 2 in Unit IV.B. of this Notice.

The risk estimates are for a 70–year lifetime and assume 40 years of exposure through application. These assumptions are also used for homegardeners applying EBDCs.

B. Final Determination on Occupational and Homegardener Exposure and Risks

As part of the Special Review process, EPA has reevaluated the exposure estimates used in estimating the risks from occupational and homegardener exposure to EBDCs. Since the publication of the EBDC PD 2/3 and the receipt of additional data required in the March 10, 1989 Data Call-In (DCI), several factors affecting occupational and homegardener exposure/risk have changed and have been used in this exposure analysis.

1. *Changes in assumptions* —a. *Usage assessments.* Revised usage assessments were prepared for EBDC use on commercial ornamentals and in cooling towers to provide a more precise assessment of occupational exposure during a 90–day use period for subchronic health effects.

The use rates used to estimate occupational exposure estimates, with the exception of homegardener uses, commercial ornamental uses, and industrial uses, are required in this Final Determination as new maximum label rates and are detailed in Unit VII.B. of this Notice (Ref. 37).

b. *Potency factor.* The estimated cancer potency, or Q_1^*, for ETU has been revised since the PD 2/3 was issued. The revised Q_1^* is 0.11 $(mg/kg/day)^{-1}$ and is discussed in Unit II of this Notice (Refs. 10 and 37).

c. *Dermal absorption factors.* Adequate data were available at the time the PD 2/3 was issued to determine the rate of dermal absorption for mancozeb (10 percent), metiram (6 percent), and nabam (9 percent). Due to a lack of adequate data, the dermal absorption rate for maneb was based on an ETU dermal absorption study (30 percent). New data required in the March 10, 1989 DCI have been submitted and reviewed. Based on these new data, the dermal absorption rate for maneb has changed from 30 percent in the PD 2/3 to 1 percent for the PD 4 (Refs. 37 and 38).

d. *Metabolic conversion factors.* Following dermal absorption, EBDCs are metabolically converted to ETU in the body. Metabolism studies used for the PD 2/3 analysis indicated that 20 percent of the absorbed EBDC is metabolically converted to ETU. These studies were reevaluated subsequent to the PD 2/3 and the metabolic conversion of EBDC to ETU was found to be 7.5 percent (Ref. 37).

e. *Conversion of EBDC to ETU in the spray tank.* In the PD 2/3, mixer/loader and applicator direct exposure to ETU in the EBDC formulation and spray solution were estimated using a limited data set. The March 10, 1989 DCI required that EBDC registrants submit tank-mix stability data for representative end-use products of all formulation types to better estimate the conversion of EBDC to ETU while in the spray tank. These data have been reviewed and accepted by the Agency. As a result of these new data, the conversion factors (i.e., the percent of EBDC converted to ETU) for maneb and metiram have changed. All conversion factors decreased with the exception of mancozeb for mixer/loaders and applicators (factors remained unchanged) and maneb for mixer/loaders (factors increased from 0.1 percent to 0.2 percent of EBDC converted) (Ref. 37).

f. *Industrial uses.* The Agency believed that the risk estimates based on agricultural exposure data may possibly overestimate exposure for nabam's industrial uses. The March 10, 1989 DCI required exposure data on oil well drilling and paper and sugar mills. The Chemical Manufacturers' Association (CMA) submitted an antimicrobial study with dermal and inhalation unit exposure estimates for these uses. The Agency has reestimated the industrial use exposure estimates based on these data. The nabam industrial exposure values derived from the CMA study reflected the range of protective clothing used in an industrial setting. Therefore, it was not necessary for the Agency to adjust the exposure values for the use of protective clothing (Ref. 37).

EPA has reevaluated the risk from occupational and homegardener exposure to EBDCs as a result of these changes. The new risk estimates are based on new required maximum label rates and assume the use of the protective clothing required by this Final Determination (except for homegardeners). The risks of concern are shown in the following Table 2:

TABLE 2.—PD 2/3 RISKS OF CONCERN COMPARED TO THE PD 4 ESTIMATES

EBDC/USE	PD 2/3 Cancer Risk	PD 4 PD Cancer Risk	PD 2/3 MOE	PD 4 MOE
Maneb/Commercial ornamentals	1×10^{-3}	1×10^{-3}	6 (Thyroid)	2,630 (Thyroid)
Maneb/Homegarden vegetables	2×10^{-5}	2×10^{-7}		
Maneb/Homegarden ornamentals	1×10^{-6}	1×10^{-7}		
Maneb/Homegarden Turf	4×10^{-4}	4×10^{-6}	60 (Develop)	400(Develop)
Maneb/Homegarden Fruit Trees	2×10^{-4}	2×10^{-6}		
Mancozeb/Homegarden Turf	7×10^{-5}	1×10^{-5}		
Mancozeb/Homegarden Fruit Trees	4×10^{-5}	6×10^{-6}		
Nabam/Paper and Sugar Mills			75 (Thyroid)	2,510
Maneb/Commercial Grapes			20 (Thyroid)	5,590 (Thyroid)

C. Comments and Response (Refs. 39 and 40).

Review of the public comments regarding occupational and homegardener exposure revealed six recurring exposure reduction suggestions: stricter protective clothing requirements on EBDC labels, reduced application rates and frequencies, increases in the reentry and preharvest intervals, changes in formulation and packaging, use of engineering controls, and restricting EBDC use.

1. *Stricter protective clothing and equipment requirements on EBDC labels.* Thirteen comments were received which stated that stricter protective clothing and equipment requirements should be required on EBDC labels. Chemical goggles, rubber gloves, coveralls, rubber boots, and suitable NIOSH approved respirators (or equivalent) were among the clothing and equipment recommended.

Commenters noted that the Agency should consider that protective clothing is not always made available, hazard training is often lacking, and the discomfort of protective clothing in hot weather may preclude use in the field. Also, commenters noted that homegardeners will probably not follow label precautions.

Response. In the December 20, 1989 **Federal Register** notice and corresponding Technical Support Document, the mixer/loader and applicator exposure estimates were reduced by 40 percent and 65 percent, respectively, to account for the protective clothing specified in the Registration Standard. Mixer/loader exposure estimates were reduced by 40 percent to account for the addition of coveralls over long-sleeved shirts and long pants (use of chemical-resistant gloves was already reflected in the original mixer/loader exposure estimates). Applicator exposure estimates were reduced by 65 percent to account for the addition of coveralls over long-sleeved shirts and long pants, and chemical-resistant gloves. Certain types of protective clothing and equipment such as goggles, face shields, chemical-resistant aprons, respirators, and rubber boots would only be used by workers handling concentrated pesticide products (i.e., mixer/loaders).

The Agency agrees that these protective clothing and equipment for mixers, loaders, and applicators may create problems due to availability, usage training, and comfort.

The use of protective clothing and equipment by harvesters and other workers reentering areas treated with EBDCs would also be expected to reduce exposure. The extent of this protection varies from crop to crop. Availability, training, and comfort are, once again, concerns that may affect the proper use of the protective equipment. These issues will be considered when the required dislodgeable foliar residue and worker reentry studies have been evaluated.

2. *Reduced application rates and frequencies.* A total of 20 comments were received on this issue. Several commenters indicated that farmers typically apply EBDCs to some crops at less than maximum rates or frequencies. In many cases, farmers were able to control diseases using fewer applications and lower rates than those indicated on EBDC labels. In addition, a user survey indicated that about one-fourth of the recommended EBDC applications are used. One commenter stated that the use of disease prediction software reduces the number of sprays per season.

Response. The occupational exposure and risk estimates reported in the PD 2/3 and the corresponding Technical Support Document were estimated using typical application rates and frequencies. Label maximum rates and frequencies were not used unless these values coincided with the typical values. Some of the typical values used are less than the reduced rates recommended in the public comments.

3. *Increase in the preharvest and reentry intervals.* Nineteen comments were received which recommended lengthened preharvest intervals for EBDCs. Several commenters recommended requiring reentry standards for specific crops. Also, a user survey indicated that longer preharvest intervals would be acceptable to Iowa vegetable growers.

Response. Lengthened preharvest intervals would be expected to reduce potential exposure to harvesters. However, preharvest intervals neither restrict nor prohibit reentry into treated fields to do nonharvesting tasks. This issue will be addressed through other label requirements (if determined necessary) when the reentry data are evaluated.

Increasing the reentry interval would be expected to reduce worker reentry exposure to EBDCs. However, at this time, insufficient dislodgeable foliar residue data have been evaluated to determine the effect of the lengthened reentry intervals recommended in the public comments. This issue will be considered further when the residue and reentry data are evaluated.

4. *Changes in formulation and packaging.* Four comments were received concerning changes in formulation and packaging. One commenter recommended a reduction in the percentage of active ingredient in the formulation. Another recommended packaging EBDCs in water soluble packets. Also, a commenter noted that a formulation such as wettable dispersable granules was recommended to reduce dermal and inhalation exposure to handlers.

Response. Dustless EBDC formulations and packaging EBDCs in water soluble packets would be expected to reduce occupational

exposure. However, insufficient data exist to quantitatively evaluate the effect of this mitigating option.

5. *Engineering controls.* One comment was received which stated that applicators should use enclosed cabs with positive pressure filtration systems.

Response. The Agency agrees that the use of enclosed cab tractors with positive pressure filtration systems would reduce exposure to EBDC applicators.

6. *Restricted use.* Two recommendations were made to make EBDCs restricted use pesticides.

Response. Making EBDCs restricted use pesticides would have no quantitative effect on estimated risk because the exposure assessment is based on pesticide use by experienced handlers.

7. *Miscellaneous comments—Comment.* (1) The Nabam Task Force has submitted to the Agency their assessment using the Chemical Manufacturers' Association's (CMA) antimicrobial study (OPP 30000/53: D–11599). The Task Force concluded that the CMA biocide exposure study fills the gap in exposure data for industrial applicators of nabam. The study was carried out using current protocols and monitored applicators carrying out application tasks typical of nabam uses. The Task Force believes that the resulting exposure data are thus much more relevant to the assessment of nabam risks than are the agricultural exposure data on which EPA previously relied. The daily exposure of nabam applicators was estimated by the Task Force to be much lower than the exposures EPA estimated in the Technical Support Document. The MOEs for thyroid effects associated with these new exposures range from 3,600 for paper mill applicators to 29,000 for cooling tower applicators. All these MOEs are well above those EPA considered acceptable. Especially in view of the small number of applicators who apply nabam, the Task Force argued that the overall risk of nabam use to workers is extremely small.

Response. The Agency found the CMA study to be useful in assessing exposures to nabam from industrial uses. However, the Nabam Task Force assessment of the CMA data was unacceptable for several reasons. First, the Task Force presented dermal exposure data from the hands instead of whole-body data. Inhalation and body exposures were also monitored in the CMA study. Even though the exposure to the hands is generally higher than exposure to other body parts, the Agency believes that all the monitoring data collected in the CMA study should be used. The total exposure estimates determined in the CMA study are representative of actual use conditions and reflect the protection afforded by protective clothing actually worn by the workers in the field. Second, the Task Force rejected certain replicates because the workers did not wear protective gloves. The Agency believes that the replicates represent typical practices in the "real world" regardless of their deviation from product labels. The inclusion of those replicates would make the database more representative of actual exposure conditions. Therefore, the Agency has used the CMA data in a manner that is more consistent with Subdivision U of the Pesticide Assessment Guidelines and reestimated the nabam exposures for the two uses addressed in the Task Force's assessment.

Comment. (2) The California Rural Legal Assistance Foundation asked if the Agency received an explanation for the observed difference in residues between sites monitored for mancozeb residues in Rohm and Haas's grape dislodgeable foliar residue study.

Response. The Agency has reviewed Rohm and Haas's explanation for the difference between the day zero mancozeb residues found in Fresno and Madera and those found in Monterey and Napa. The maximum label rate for application of the product used in the study to grapes is 3.2 lb. a.i./acre. However, sites in Monterey and Napa received applications at rates of 6.7 and 4.5 lbs a.i./acre, respectively. Therefore, data collected at these two sites are inappropriate for the reentry exposure assessment.

V. Summary of Benefits Assessment and Agency Evaluation of Comments and Additional Data Received

A. Synopsis of Benefits Assessment

1. *Overview of comments received.* EPA received over 200 comments on the Preliminary Determination (PD 2/3) benefits assessment. The majority of comments supported the continued use of EBDC products but did not contain scientific data supporting the usefulness of the EBDCs to control plant diseases. The Agency was also able to obtain and examine useful data for many sites. A variety of sources were used to determine the usefulness of such comments, including the 1991 National Agricultural Pesticide Impact Assessment Program (NAPIAP) Fungicide Benefits Assessment (Ref. 24), published comparative performance data, communications with agricultural specialists familiar with the diseases and the crop in question, in-house expertise, proprietary sources, books, and professional journals. EPA considered the information provided by agricultural specialists reliable based upon the Agency's understanding of the epidemiology of the disease and agricultural practices for the crop in question. The estimates are provided as but one opinion because the Agency cannot document the basis for these opinions. Generally, estimates based on information from NAPIAP are secondary sources of information. Such estimates are more fully described in the benefits site analyses which are available in the EBDC public docket. These estimates are expressed in ranges where possible. These estimates may be subject to uncertainty, particularly where data from studies were not available.

In some instances the information provided in the comments did not result in significant quantitative changes between the preliminary and final benefits assessment. One example is peppers. Comments in response to the PD 2/3 on peppers addressed the importance of the use of EBDCs in combination with copper for control of bacterial spot. For the PD 2/3, the Agency was not aware of this use of EBDCs because control of bacterial spot is not claimed on the pesticide's label. Further investigation led the Agency to revise its estimates which resulted in only a minor increase in the estimated average benefits of EBDCs on peppers. The Agency did adjust its benefits assessment taking this information into account. The average total impact increased from $73.5 million to $82.5 million.

In other cases, such as with oats, comments and efficacy data which the Agency obtained made a significant difference in the final analysis. Commenters stated that oat varieties previously resistant to crown rust are displaying an increasing incidence of crown rust due to a new race of the fungus. Crown rust is a fungal disease not listed as a disease mancozeb controls on small grains; however, EBDCs are efficacious against a related rust disease, leaf rust, on small grains. Due to the similarity of the two diseases, the Agency assumes that mancozeb is likely to control crown rust as well. Sulfur, the only registered alternative fungicide to EBDCs on oats, is not effective for control of crown rust. This new information has resulted in an increase in the EBDC benefits assessment for oats ranging from $0.1 to $0.5 million in the PD 2/3 to $3.8 million to $25 million in the PD 4.

2. *Total benefits.* In the PD 2/3, the Agency estimated that cancellation of

all EBDC registrations for all food crops would result in a direct first-year loss to growers (i.e., direct producer impacts) of approximately $46 to $75 million. Beyond the grower impacts, the Agency estimated total losses to society (i.e., efficiency impacts) to be $90 to $305 million. The estimated total losses to society (i.e., efficiency impacts) are the net impacts of losses and gains of the EBDCs to producers (users and non-users), distributors, and others in the marketing chain, as well as the final consumers. The estimated impact of cancellation of non-food uses and industrial sites was expected to not exceed $1 million.

The Agency has revised its site-by-site and aggregate benefits estimates for all 56 sites based on the public comments received, the NAPIAP report, and additional research. EPA now estimates total first-year EBDC impacts in the range of $290 to $630 million. Of this total, direct producer impacts constitute approximately $140 to $282 million. The remaining impacts are consumer and efficiency impacts. No specific comments were received regarding non-food uses; therefore, the $1 million estimate for non-food uses as reported in the PD 2/3 remains unchanged.

While the total benefits (i.e., economic impacts) may appear significant, the high estimate of $630 million represents less than 1 percent of the total 1989 United States farm value of production. Based on average retail values, the overall impact on consumers would be proportionally less than the farm level impacts. The Agency has estimated a nationwide total benefits range but understands the potential for severe regional impacts. For example, leafy green growers in the southeastern region of the United States are likely to face economic impacts far more severe than leafy green growers in other areas. In addition, potato growers in the Northeast, Florida, and Wisconsin may face significant secondary impacts in the cultivation of crops not treated with EBDCs because of rotational restrictions on use of the major alternative, chlorothalonil.

The total benefits estimate is projected for only the first year following the loss of EBDCs. This estimate assumes no acreage or import/export adjustments during this first year. In addition, the availability of alternatives and (for the most part) efficacy of alternatives is assumed constant for the first year. These assumptions may result in an overstatement of benefits if growers were able to make gradual adjustments in response to the unavailability of the EBDCs.

3. *EBDC usage.* In the PD 2/3, the Agency estimated total average annual EBDC usage over the 1986 to 1988 period in the range of 12 to 16 million pounds active ingredient. The largest individual usage sites, by volume, included apples, cucurbits, onions, potatoes, small grains, sweet corn, and tomatoes. Important use sites in terms of percent of crop treated included apples, cucurbits, leafy greens, lettuce, onions, peppers, potatoes, and spinach. The Agency has revised its total annual EBDC usage estimate based on additional information received in response to the PD 2/3. Total average annual usage for a "typical" current year (prior to 1990) is now estimated at approximately 8 to 12 million pounds active ingredient.

The broad spectrum of activity of EBDCs and their relatively low cost have made them widely used fungicides. EBDCs also have a multi-site mode of action (i.e., affecting 2 or more enzyme systems) and are used in some cases to slow or prevent the development of fungal resistance, which is more likely to occur with fungicides that have more limited modes of action. For example, EBDCs are used in combination with metalaxyl on potatoes for control of late blight. EBDCs applied with metalaxyl reduce the development of late blight isolates resistant to metalaxyl.

EBDCs are also found to have a synergistic effect with copper, increasing the ability of copper to control bacterial diseases compared to copper applied alone. This is important in the control of bacterial speck on tomatoes and bacterial spot on peppers and tomatoes.

EBDCs may play an important role in Integrated Pest Management (IPM) practices. University scientists have developed disease forecasting systems to determine environmental conditions favorable for disease development. These forecasting systems have led to the more judicious applications of EBDCs during disease outbreaks. Examples are potato late blight control programs and apple scab control programs. The successful use of EBDCs on apple IPM programs is discussed in Unit V.B.

EBDCs are registered for use on many minor vegetable and fruit crops for which there are limited available field trial data, production cost figures, usage data, and other information typically used by the Agency to quantify benefits. Nonetheless, the Agency believes the continued use of EBDCs on many of these minor crops does provide benefits to users and society. For example, even though the benefits cannot be quantified for almonds, apricots, asparagus, caprifig, crabapple, fennel, pecans, pineapple, quince, rhubarb, and sugar beets, inhibiting fungal resistance to other fungicides is one benefit demonstrated by EBDCs. For other crops such as eggplant and endive, there are no viable alternatives. Yield losses are likely for eggplant and endive where the only alternatives are copper fungicides which are phytotoxic.

4. *Alternative fungicides.* The Agency considered chlorothalonil to be the most widely used alternative fungicide to replace EBDCs for fungal disease control. Several comments in response to the PD 2/3 indicated that crop rotations would be restricted with the use of chlorothalonil, a restriction not present with EBDCs. The chlorothalonil label states that fields treated with chlorothalonil cannot be rotated with crops not listed on the chlorothalonil label for 12 months after treatment. The Agency is aware that dry bean, potato, seed corn, tomato, and other growers practice a variety of crop rotations depending on agronomic reasons such as plant disease control. The quantification of these benefits was difficult as was the quantification of other EBDC benefits such as the fungicide's use in pest resistance management. However, when possible, EPA provided quantitative estimates of such benefits as well as considering the qualitative benefits in the final assessment.

B. Site-Specific Summaries

The following paragraphs are summaries for sites where there was a significant change in the estimated impacts. These revisions are based on rebuttals to the original analyses and other new information that became available to EPA subsequent to publication of the PD 2/3. Sites summarized below include: apples, leafy greens (i.e., collards, kale, mustard greens, and turnip greens), papaya, potatoes, and tomatoes. The complete assessments for all 56 sites is available (Ref. 32).

1. *Apples.* Mancozeb, maneb, and metiram are registered to control several important fungal diseases on apples. The registered alternatives to EBDC fungicides include benomyl, captan, copper fungicides, dodine, fenarimol, thiophanate-methyl (TM), triadimefon, and triforine. However, none of these fungicides are considered to be a universal substitute for the EBDC fungicides. Fungal resistance to benomyl and TM has developed, reducing the

ability of these two systemic fungicides to control apple diseases in orchards.

The Agency received comments in response to the EBDC PD 2/3 supporting the continued EBDCs use on apples from a variety of sources including the EBDC/ETU Task Force, apple growers, university scientists, and the International Apple Institute (IAI). Many of the comments addressed the ability of captan, which is incompatible with mineral oil, to replace EBDCs. Mineral oil is applied at the same time EBDC fungicide applications are made for control of apple scab.

Mineral oil is used to decrease early season mite populations. This early mite population control reduces the total number of miticide applications needed during the course of the apple growing season. One of the major alternatives to EBDCs, captan, cannot be used with mineral oil because this combination is phytotoxic to apple foliage. Thus, if the use of EBDCs are cancelled on apples and is replaced by captan, the Agency believes that this would result in an increase of 1 to 2 additional miticide applications in lieu of mineral oil during the growing season and would have a negative impact on apple IPM programs.

Commenters also expressed concern that without the use of EBDCs, additional chemical applications would be needed on apples. The commenters indicated that EBDCs are the most efficacious fungicides for control of summer diseases. The Agency estimated that additional captan applications used in combination with benomyl would be necessary to achieve comparable efficacy for summer disease control. Assuming that information gathered from NAPIAP, other comments, and university scientists familiar with apple pathology is correct, up to 3 additional captan applications may be required depending upon the apple growing region. In the Northeast, mancozeb provides a supplemental nutrient source of zinc. Apple soils in this area are deficient in zinc, a necessary micro-nutrient for apple production. The Agency estimates that 1 to 2 additional zinc applications would be necessary in this region in the absence of EBDCs.

In the PD 2/3, the Agency estimated approximately 48 percent of all United States apples were treated with EBDCs. The cancellation of EBDCs was estimated to result in a net producer loss of $0.3 million to $10.3 million. Consumer impacts were not quantified.

Revised usage estimates indicate that approximately 48 to 50 percent of the total United States apple acreage is treated with EBDC chemicals in a typical year. Based on comments and data, the Agency estimates as it did in the PD 2/3, that aggregate EBDC user production could decline by about 9 percent. The Agency now estimates total EBDC first-year benefits at approximately $51.8 million. Growers are expected to face both price adjustments and increased production costs. Consumers are estimated to pay about 2.5 to 3.5 percent more for apples.

2. *Leafy greens (collards, kale, mustard greens, and turnip greens).* Maneb has been used for control of fungal leaf spot diseases on leafy greens with a Special Local Needs registration for the use of the fungicide in Georgia. Leafy greens do not appear on the current Federal maneb label. Historically, maneb has been used to treat 90 percent of the leafy green crops.

In the PD 2/3, the Agency estimated a complete crop loss on the second cut of the leafy greens without the use of EBDCs. In response to the PD 2/3, data were submitted on the efficacy of maneb for control of fungal leaf spot on turnip greens. Based on these data, the Agency estimates that, without the use of EBDCs, approximately 50 percent of the fall second cutting would be unacceptable, according to USDA grading standards for processing, due to fungal leaf spot. EPA also assessed the effect of EBDCs on the spring leafy green crop and observed no significant differences between EBDC and untreated controls in terms of fungal leaf spot control. However, leafy green producers prefer to grow the fall leafy green crop due to climatic conditions which reportedly produce a more succulent crop. Thus, the Agency estimated from these data that growers would incur a 25 percent yield loss (50 percent decrease in yield on the fall second cutting) if the use of EBDCs is cancelled for leafy greens. The Agency estimates that yield losses could be higher if a third cutting were attempted. Assuming information on this site as presented in the 1991 NAPIAP report is correct, yield losses could be as high as originally stated in the PD 2/3 (i.e., 50 percent) if environmental conditions favor disease.

EBDC benefits were not quantified for the PD 2/3 due to the lack of data available to the Agency. Current first-year producer benefits are estimated as follows: collards ($5.7 to $13.7 million), kale ($2.1 to $5.0 million), mustard greens ($4.1 to $9.7 million), and turnip greens ($3.2 to $7.6 million). Consumer and community impacts may occur, although no quantitative measure could be obtained.

3. *Papayas.* Mancozeb is used on papayas to control anthracnose and Phytophthora fruit rot. Hawaii encompasses 95 percent of the United States papaya production; 100 percent of the papaya acreage in the state is reported to be susceptible to Phytophthora fruit rot. Information supplied to the Agency since the PD 2/3 indicates that 100 percent of all papaya acreage in Hawaii is treated with mancozeb to control this disease. The Agency does not have EBDC usage data for Florida.

EBDCs reportedly provide benefits not realized with chlorothalonil. Quarantine regulations require Hawaiian papaya shipped to the mainland United States to be treated to prevent the transmission of fruit flies. Information submitted in response to the EBDC PD 2/3 indicates a phytotoxic response when chlorothalonil-treated papaya fruit are later treated by either of the usual quarantine methods, which are double hot water and vapor and dry heat. The data indicated that chlorothalonil-treated fruit followed by a double hot water dip resulted in an average of 85.8 percent of the fruit being scalded (browning of papaya fruit) on at least 10 percent of the surface area. Similar results are to be expected with the vapor and dry heat method. This scalding of the fruit results in the fruit being unmarketable. Therefore, the Agency does not consider chlorothalonil to be a viable alternative to EBDCs for control of fungal diseases on papaya in Hawaii.

Florida papaya fruit are not subject to the same quarantine restrictions as the Hawaiian fruit. Hence, the heat treatments discussed above do not have to be used. Thus, Florida growers can use chlorothalonil without having a concern for scalded fruit. Commenters submitted data comparing chlorothalonil and EBDCs for control of Phytophthora fruit rot. Based on the information submitted, the Agency estimates a 6 percent decrease in yields in the absence of EBDCs for Florida papaya growers applying chlorothalonil. No decrease in efficacy is anticipated with replacing EBDCs with chlorothalonil for control of anthracnose.

For the PD 2/3, data were not available to accurately quantify the benefits of EBDCs on papayas. Based on the comments received, the Agency estimates the benefits of EBDCs for papaya could be as high as $8 million representing about 54 percent of the estimated total 1989 value of United States papaya production. Consumer impacts have not been quantified but are expected to be significant in terms of the current retail market value. The possibility of a rapid production transfer from Hawaii to Florida has not been determined.

4. *Potatoes.* Mancozeb, maneb, and metiram are used to control early blight and late blight as well as fungi identified in potato seed-piece decay. EBDC foliar applications are made to an estimated 56 percent of the total United States potato acreage. Alternative fungicides registered for use on potatoes include: anilazine, chlorothalonil, copper compounds, formaldehyde, metalaxyl, streptomycin, TM, thiabendazole, and triphenyltin hydroxide (TPTH). However, there is no one alternative fungicide registered to control all the potato diseases for which EBDCs are registered.

The Agency has information which suggests that applications of TPTH at label rate result in a phytotoxic response to potatoes. Applications of TPTH at a reduced rate and a reduced rate of mancozeb together have been efficacious for control of early blight without burning potato foliage. If EBDCs are cancelled on potatoes, growers would resist using TPTH due to phytotoxic concerns with the fungicide. Early blight resistance to another registered alternative fungicide, iprodione, has limited the usefulness of iprodione in the future.

In the PD 2/3, the Agency concluded that for foliar diseases, the EBDCs and chlorothalonil are more efficacious than their registered alternatives and that chlorothalonil combined with metalaxyl is somewhat more effective than EBDCs. The Agency received several comments disagreeing with the Agency's conclusion that chlorothalonil is more efficacious than mancozeb. Based on a review of comparative performance studies used for the PD 2/3 analysis and data submitted as comments on the PD 2/3, the Agency believes that although applications of chlorothalonil may result in less early or late blight, there are no significant yield differences realized between treatments of chlorothalonil and mancozeb.

Commenters also addressed crop rotation restrictions with chlorothalonil. Potato growers in the western United States mainly use EBDCs to control early blight. In the absence of EBDCs, the Agency assumed that western growers would switch to anilazine because of the crop rotation restrictions following the application of chlorothalonil. The increased costs of anilazine were incorporated into the revised assessment. Data submitted indicate that anilazine used to control early blight provides yields similar to the yields achieved with EBDCs.

Data indicate that late blight is a disease that can cause significant yield losses in New England. Yield losses occur to a lesser extent in Florida, New York, Pennsylvania, and Wisconsin due to the differences in climatic conditions. Based on the NAPIAP report and data published in Fungicide and Nematicide Tests (Ref. 41), the Agency estimates that yield losses can average 50 percent on untreated potato plants and can reach 100 percent under heavy disease pressure. Without the use of EBDCs, growers would need to use the chlorothalonil/metalaxyl combination for late blight control rather than the EBDC/metalaxyl combination. This would force growers to rotate potatoes with crops on the chlorothalonil label to legally use the chlorothalonil/metalaxyl fungicide. Potato producers switching to the chlorothalonil/metalaxyl alternative would be subject to rotational restrictions.

For the PD 2/3, the Agency estimated total annual EBDC benefits on potatoes at approximately $0.4 million. Based on data and comments received, the Agency's estimated impact was revised to approximately $40 million which represents approximately 2 percent of the total 1988 value of United States potato production. The Agency's estimate is based on the assumption that alternatives are equally efficacious. The estimate represents aggregate production cost impacts using alternative controls for both seed-piece and foliar needs. The Agency anticipates negligible impacts to producer gross revenues and to consumers.

Rotational restrictions are not included in the benefit estimate presented above. As discussed above, the Agency is aware of rotational restrictions with use of the chlorothalonil/metalaxyl alternative which may result in additional impacts to growers. Based on information submitted by commenters, the Agency estimates that total secondary rotational impacts may be as high as $52 million in the northeastern potato growing regions. Assuming this information is correct, this would be in addition to any potential impacts in Florida and Wisconsin. The Agency believes some secondary impacts may occur but does not have sufficient economic data to support or refute the assumptions used for this estimate.

5. *Tomatoes.* EBDCs are used on tomatoes to control anthracnose, early blight, late blight, gray leaf spot, gray leaf mold, and septoria leaf spot. The Agency estimates that 30 to 40 percent of the United States tomato acreage is treated with EBDCs. Registered alternatives to EBDCs include anilazine, benomyl, captan (plant bed only), chlorothalonil, various copper compounds, dichlone, dicloran, ferbam, and metalaxyl. In the absence of EBDCs, the Agency estimated that tomato growers would switch to chlorothalonil for disease control.

Many of the comments to the PD 2/3 focused on applications of copper and EBDCs tank-mixed together to control bacterial spot and bacterial speck. For the PD 2/3 analysis, the Agency did not consider the use of EBDCs for control of bacterial diseases on tomatoes because EBDC labels did not list bacterial diseases as pests controlled. Thus, the Agency was not aware of a common grower practice of mixing copper and EBDCs for bacterial disease control on tomatoes. The Agency acknowledges that bacterial diseases are important and that the data available indicate that EBDCs increase the efficacy of copper for controlling these diseases on tomatoes.

Historically, copper has been used to control bacterial diseases on tomatoes. However, the development of bacterial isolates resistant to copper has reduced the efficacy of copper. Copper-resistant bacterial spot isolates have been reported in many tomato growing regions. Bacterial spot isolates previously resistant to copper become susceptible to the copper/maneb combination. Scientists speculate that this increase in efficacy is due to a synergistic reaction occurring between the two pesticides when they are tank mixed.

Studies have indicated that growers can substitute maneb and copper with chlorothalonil and copper and achieve equal efficacy when only bacterial spot isolates susceptible to copper are present. However, unlike maneb, there are no data available indicating a synergistic reaction occurring between a tank-mix of chlorothalonil and copper. Due to this lack of synergy, the combination of chlorothalonil and copper may not be effective in situations when copper insensitive isolates are present. Data submitted in response to the PD 2/3 indicated that affected tomato growers could incur yield losses as high as 20 percent if bacterial spot is not controlled. No estimate of the lower bound yield loss was available.

EBDCs and copper are also applied to control bacterial speck, specifically in the Northern tomato growing region. Bacterial speck is of concern early in fruit development with the disease usually being of little concern when the fruit is ready for harvest. Data submitted in response to the PD 2/3 indicated that tomato fruit had significantly less bacterial speck infection when treated with EBDC/copper combinations compared with chlorothalonil/copper

combinations. Under heavy disease pressure, the Agency estimates that growers can expect a 5 to 10 percent yield loss.

Commenters responding to the PD 2/3 also questioned the ability of chlorothalonil to act as a replacement for EBDCs on tomatoes in California. The commenters submitted data disagreeing with the Agency's PD 2/3 estimate of an increase in efficacy with chlorothalonil compared to EBDCs for control of black mold. The commenters also stated that crop rotation restrictions with chlorothalonil limit the use of the fungicide in California.

Based on the data submitted, the Agency agrees with the commenter that chlorothalonil is as efficacious as EBDCs for control of black mold. The Agency is aware, from comments to the PD 2/3, that California tomato growers rotate tomatoes with crops not included on the chlorothalonil label. This will be of potential concern to California tomato growers who use EBDCs to control black mold and late blight if they choose to rotate to crops not on the chlorothalonil label. These growers could switch to anilazine without changing their rotations and without any decrease in efficacy. The increased cost of anilazine was incorporated into the revised benefits assessment.

The benefits for tomatoes have increased from the PD 2/3 estimate of $0.1 million to the current estimate of $32 million to $45 million. This increase is due to: (a) A revised percent-crop treated estimate; (b) Updated yield loss projections; and (c) Revised cost estimates on the likely alternative fungicides. The current benefits represent approximately 3 percent of the total 1989 value of the United States tomato production.

C. Response and Comments: General

1. *Comment.* The American Farm Bureau submitted comments supporting the continued use of EBDCs. The commenter stated that the Agency understated the benefits of EBDCs and highlighted several issues concerning the Agency benefits analysis including: (a) The Agency should recognize economic data submitted in response to the PD 2/3; (b) EPA failed to consider the efficacy of alternative fungicides; (c) EPA did not consider the label constraints of alternative fungicides; (d) The Agency did not consider the affect of selected alternative fungicides on crop safety (e.g., phytotoxicity); and (e) EPA did not consider the total available supply of alternative fungicides.

Response. The Agency has considered the comparative efficacy of alternative fungicides to EBDCs and possible label restrictions. One example is crop rotation restrictions with chlorothalonil. The chlorothalonil label states that crops not listed on the fungicide's label cannot be rotated with chlorothalonil-treated crops for 12 months. This information is reflected in the Agency's benefits analysis. The Agency has assessed the viability of alternative fungicides to EBDCs, the availability of the fungicide, and possible phytotoxic responses to the crop when the alternative fungicide was applied. One example is copper. Copper is registered to control many of the same diseases as EBDCs. The Agency was aware that applications of copper can injure foliage of several crops such as lettuce and spinach. Also, the Agency considered the present and future availability of alternative fungicides to EBDCs as part of the Agency's benefits analysis.

2. *Comment.* The EBDC/ETU Task Force submitted comments highlighting the benefits of EBDC fungicides for control of plant diseases. Their comments included information and data on the benefits of EBDCs for 10 crops: apples, bananas, cucurbits, grapes, onions, peanuts, potatoes, small grains, sweet corn, and tomatoes. The EBDC/ETU Task Force also submitted data on fungicide resistance including information on fungal resistance to EBDCs and alternative fungicides.

Response. Information and data provided by the EBDC/ETU Task Force were used as part of the Agency's benefits assessment. Detailed responses to the Task Force's comments on apples, grapes, peanuts, potatoes, small grains, sweet corn, and tomatoes are discussed in Unit V.D. of this document.

3. *Comment.* The Florida Farm Bureau Federation submitted comments supporting the continued use of EBDCs on certain agricultural crops. A survey of pesticide usage by the Florida Farm Bureau Federation members was included in their comments. Other information was included on their analysis of the projected impact of cancellation of EBDC fungicides on fruit, small grain, and vegetable production in Florida.

Response. The Agency appreciates pesticide user groups conducting surveys on pesticide usage by its membership. The information included in the Florida Farm Bureau Federation survey was useful, along with other information, for the Agency in terms of assessing pesticide usage, alternative fungicides, and diseases the fungicides control. The data highlighting the possible impact of the loss of EBDCs to crop production were incorporated in the final benefits analysis.

4. *Comment.* GRC Economics, on behalf of Atochem North America, submitted comments (which included information based on results from the NAPIAP report), supporting the continued use of EBDCs. The commenter also stated that crop rotation restrictions on the chlorothalonil label limit the usefulness of the fungicide as a substitute to EBDCs for potatoes and tomatoes.

Response. EPA used the NAPIAP report and other information to assess the possible impact of the cancellation of EBDCS on agricultural crops. Estimates provided in the NAPIAP report were considered in the Agency's final benefits assessment. The Agency recognizes that crop rotation restrictions are present with applications of chlorothalonil and that the chlorothalonil label states that fields treated with chlorothalonil cannot be rotated with crops not listed on the chlorothalonil label. This type of limitation does not appear on EBDC labels. This potential limitation is reflected in the Agency's final benefits assessment.

5. *Comment.* Hogan and Hartson, on behalf of the Rohm Haas Company, submitted comments supporting the continued use of EBDCs on agricultural crops. Hogan and Hartson commented on several issues of the EBDC PD 2/3 benefits analysis including: (a) The need for apple growers to apply additional captan applications to compensate for the absence of EBDCs; (b) The incompatibility of captan and mineral oil on apple foliage; and (c) Crop rotation restrictions for the use of chlorothalonil, propiconazole, and triadimefon on potatoes and small grains, respectively.

Response. The Agency realizes that if this information is correct and growers replace EBDCs with captan, additional pesticide applications may be needed. The Agency estimates up to three additional captan applications might be needed to achieve comparable disease control to EBDCs. One to two additional captan applications may be required in the mid-Atlantic apple growing region and two to three additional captan applications in the Northeast. Due to the incompatibility of captan and mineral oil, the Agency estimates growers would need to replace the use of mineral oil with one to two additional miticide applications per growing season. Crop rotation restrictions are present on the chlorothalonil, propiconazole, and triadimefon labels. The fungicide labels restrict crop rotations to crops that are listed on the particular fungicide's label for a specific period of time. In the case

of chlorothalonil, the fungicide label states that fields treated with chlorothalonil cannot be rotated with crops not listed on the chlorothalonil label for 12 months. The Agency is aware that growers practice a variety of crop rotations depending on agronomic factors.

6. *Comment.* The National Food Processors Association (NFPA) submitted comments in support of the continued use of EBDCs on agricultural crops. Their comments were based on a study conducted by NFPA and depicts the 1989 usage of EBDCs, the availability of alternatives to EBDCs, and the benefits of the fungicide. NFPA directed their comments toward the importance of EBDCs on apples, broccoli, carrots, grapes, pears, peppers, potatoes, spinach, sweet corn, and tomatoes.

Response. The Agency appreciates the increased user group involvement. The information from comments and responses to the surveys by NFPA were examined by the Agency in its final benefits analysis.

D. Crop-Specific Comments and Response

1. *Comment on the importance of EBDCs to apple cultivation.* Growers submitted comments stating the importance of mancozeb on apples. Specifically, 2 growers mentioned that mancozeb is used as a supplemental source of zinc in addition to its disease control properties

Response. For the PD 2/3 analysis on apples, the Agency was not aware of mancozeb's role as a source of zinc fertilizer. EPA has further examined this issue and now estimates northeastern apple growers would apply one to two additional zinc micro-nutrient applications if EBDCs were cancelled. The additional expenses for northeastern apple growers was factored into the final benefits analysis.

2. *Comment supporting the continued use of EBDCs on apples.* The EBDC/ETU Task Force, as well as apple growers, submitted comments supporting the continued use of EBDCs on apples. The Task Force stated that captan is not as efficacious as EBDCs for control of summer diseases (i.e., bitter rot, fly speck, and sooty blotch). They indicated that if EBDCs were not available to apple growers, three additional captan applications would be needed to compensate for captan's lack of efficacy compared to the EBDCs. The Task Force also commented on the compatibility of EBDCs and mineral oil. Mineral oil is used to reduce early season mite populations. However, applications of captan and mineral oil have resulted in a phytotoxic response to apple foliage. They remarked that an increase in miticide applications would be necessary if EBDCs are cancelled on apples.

Response. The Agency acknowledges that in the absence of EBDCs, an increase in the number of captan applications may be necessary, especially for control of summer diseases. The Agency estimates that one to three additional captan applications may be necessary to compensate for the cancellation of EBDCs depending on the apple growing region. This information was incorporated in the Agency's analysis. The Agency agrees that captan applied in combination with mineral oil is phytotoxic to apple foliage. If EBDCs are cancelled on apples, this would be detrimental to apple IPM programs. The Agency estimates that one to two additional miticide applications may be needed in the absence of EBDCs.

3. *Comment on EBDC usage for apples.* Fungicide usage information on Michigan apples was submitted as a joint report by the Michigan State University Cooperative Extension Service, Michigan Processing Apple Growers, and the Michigan Farm Bureau. The IAI also submitted fungicide usage information on apples in addition to data supporting the continued use of EBDCs on the crop. The commenters stated that: (a) EBDCs are the most effective fungicide for control of bitter rot, fly speck, and sooty blotch; (b) Reduced rates of EBDCs are applied to apples and have been found to be efficacious; (c) Quality impacts were not quantified in the PD 2/3; (d) EBDCs are important in terms of fungicidal resistance management; (e) EBDC use varies by geographic region; and (f) The cost of the registered alternatives will change if EBDCs are cancelled.

Response. The Agency appreciates the information from both surveys. This information helped EPA to have a better understanding of chemical usage on apples. Both surveys were examined in by the Agency in its final benefits assessment.

In response to the first point, EPA believes that applications of benomyl in combination with captan are as efficacious as EBDCs for control of summer diseases. However, additional captan applications would be needed to achieve this efficacy. The Agency estimates that one to three additional captan applications may be needed in the absence of EBDCs depending on the apple growing region.

With respect to the second point, EPA agrees that apple growers may find EBDC fungicides applied at a reduced rate to be effective. However, under heavy disease pressure, the Agency estimates that the full label rate may be needed for efficacious disease control. This will vary depending on the specific disease being targeted and the geographic location. For the purpose of estimating the cost of fungicide applications, the Agency assumed that the maximum application rate is used.

The Agency considered regional diversity and corresponding usage and economic impacts for the PD 2/3 and for this Final Determination. The Agency has examined its analysis to further reflect this diversity. Information on regional impacts are incorporated into the analysis.

Along with their estimated annual short-term benefits, the EBDCs may also have some long-term benefits for apple production. The Agency believes that without the use of EBDCs on apples, it may be possible that there could be a permanent economic decline to selected apple growers in limited areas. Consumer impacts are likely to be minor to negligible as adjustments are made in production and trade patterns.

With respect to quality impacts, EPA in the PD 2/3 qualitatively evaluated a decrease in apple quality and concluded that any anticipated quality impact would be minor, falling within the benefit range identified. This assumption is carried into the current estimates.

Fourthly, the Agency is aware that EBDCs have often been relied upon to slow or prevent the development of fungicide resistance on apples. One example is EBDC use in combination with benomyl or ergosterol biosynthesis inhibitor fungicides.

Regarding geographic variation, EPA considered regional usage of EBDCs in both the PD 2/3 and in this Final Determination. For the PD 4, the Agency reviewed the IAI survey in examining regional variation in fungicide usage. The IAI survey is generally consistent with the NAPIAP data. The primary difference is that the IAI survey identifies higher usage in the Southeast than that used by the Agency (i.e., 97 percent vs. 86 percent).

Finally, EPA is aware that Agency action can increase the costs of alternative controls and crop production. These factors have been taken into account. The revised cost analysis now indicates a net cost increase to growers with the use of alternatives.

4. *Comment supporting the continued use of EBDCs on bananas.* The International Banana Association submitted comments supporting the continued use of EBDCs on bananas. They stated that black sigatoka is a

devastating disease to banana growers and must be controlled for the banana industry to survive; it is the greatest single plant disease threat to food production in the tropics and to the worldwide banana industry. Further, the commenter stated that because of intrinsic differences in their climatic and cultural practices, Hawaiian producers cannot be considered representative of the South and Central American growers who supply the large majority of bananas to the United States market. In its own analysis, the Association has determined that the loss of one or both of the EBDC fungicides will lead to increased dependence on systemic fungicides, foster development of resistance to available fungicides, and place both the world banana industry and local tropical agriculture at a grave risk.

Response. The Agency recognizes that increased dependence on systemic chemicals and increased pest resistance to available fungicides may to occur over time. However, no specific yield loss estimates are available to allow the Agency to quantitatively address the impacts.

5. *Comment on the benefits and use of EBDCs on bananas.* A commenter stated that in the PD 2/3, the Agency underestimated the benefits and overestimated the usage of EBDCs on bananas in Hawaii. The commenter indicated that grower yield impacts of $2.1 to $4.1 million could result from yield and fruit quality losses caused by the black leaf streak disease in Hawaii if the EBDC fungicides were cancelled.

Response. Additional information available to the Agency since the PD 2/3 indicates 100 percent of all banana acreage in Hawaii is treated with EBDCs. Data were not submitted to support the yield impact in the absence of EBDCs. The Agency has no data to support or refute the estimated yield impacts to growers.

6. *Comment on carrots.* One Wisconsin commenter supported the continued use of EBDCs on carrots and proposed amending the mancozeb label to extend the preharvest interval of EBDCs on carrots from 7 to 21 days. The commenter suggested that this would result in reducing residues without compromising efficacy. Other suggested amendments to the label included supporting the use of IPM programs already adopted by carrot growers in his State. One example of an IPM program was the use of weather monitoring programs to more accurately depict increases in disease development and more judicious fungicide applications.

Response. The Agency appreciated the material provided. This type of information assists the Agency in evaluating possible label changes for mancozeb intended to reduce the risk of the fungicide while maintaining disease control. The provided data support the proposed label changes for Wisconsin; however, the changes may not be applicable to other carrot growing regions.

7. *Comment on broccoli, brussels sprouts, cabbage, and cauliflower.* GRC Economics, on behalf of Atochem North America, commented that crop rotation restrictions on the chlorothalonil label limit the usefulness of the fungicide on cole crops.

Response. The Agency is aware of the crop rotation restrictions associated with the use of chlorothalonil. However, the commenter did not supply data that would allow the Agency to determine the impact of this restriction on cole crop production.

8. *Comment on cotton.* The National Cotton Council of America and the Trans-Pecos Cotton Association, among others, submitted comments supporting the continued use of EBDCs on cotton. The commenters said that EBDCs are needed to control cotton rust in the southwestern United States cotton growing region. Arizona and the National Cotton Council indicated that yield losses have been reported to be as high as 50 to 75 percent if cotton rust is not controlled.

Response. No data were submitted by commenters to support these yield loss estimates. The estimates provided to the Agency are considered to be opinion, as opposed to actual data.

9. *Comment on the importance of EBDCs to cucurbit cultivation.* One commenter stated that EBDCs are critical to watermelon producers because plant breeders have not developed watermelon varieties resistant to fungal plant pathogens. Research has demonstrated that without the use of EBDCs, losses due to some foliar pathogens can exceed 75 percent. Estimates indicated that during the previous 5 years, about 70 percent of the watermelon acreage was treated with one or more EBDC compounds, or combinations of an EBDC compound with other fungicides.

Response. The Agency recognized the importance of fungicides in cucurbit production in the PD 2/3. Estimated impacts to the cucurbit markets due to loss of EBDCs were based on the relatively higher cost of chlorothalonil. These impacts ranged from an estimated $3.8 million to $8.6 million annually. No yield impacts were anticipated based on available comparative product performance data. USDA estimates for yield losses were up to 10 percent for melons, but there is no information to support the yield loss estimate of 75 percent for watermelon if the EBDCs were no longer available. However, Agency scientists believe that this yield loss estimate is probable if there are no controls for the foliar problems on watermelons; however, in actual practice, alternative control will be employed and any yield loss minimized.

10. *Comment on alternative fungicides for cucurbits.* One commenter stated that if the EBDCs were not available for use on cucurbits, chlorothalonil would be the major alternative to control foliar fungal diseases. Such an action would result in an impact for growers who switch to chlorothalonil and also experience viral diseases on cucurbit acreage. Mineral oil, which is compatible with EBDCs, is used to control the insects that spread the virus. Combinations of chlorothalonil and mineral oil applications result in phytotoxicity.

Response. The Agency has no data to quantify yield losses due to aphid-borne viruses on cucurbits. The commenter knew of no way to quantify losses from viral diseases because such studies have never been done. The Agency has considered the projected increase in the cost of production, taking into account the production cost changes for insecticides compatible with chlorothalonil to control aphid-feeding, as recommended in IPM programs, especially in Florida.

11. *Comment on dry beans.* The Agency received comments from North Dakota State University and Colorado State University in response to the EBDC PD 2/3 indicating that chlorothalonil had rotational restrictions that would make it an inappropriate alternative for control of rust on dry beans.

Response. The 2 registered alternative fungicides that are available to control rust on dry beans are chlorothalonil and sulfur. Chlorothalonil provides effective control; however, it has rotational restrictions on the label stating that a crop that does not appear on the label cannot be planted in a chlorothalonil-treated field for up to a year after the last chlorothalonil application. The only other alternative is sulfur which is not effective against rust.

A majority of the dry bean producing states are in climatic zones that are not favorable to disease development. However, there are 2 main bean-producing regions that may be affected by rust. The largest is the bi-state area of Minnesota and North Dakota. The second is Colorado and surrounding areas consisting of northwestern

Kansas, southwestern Nebraska, northeastern New Mexico, northwestern Texas, and southeastern Wyoming. In both regions rust is an intermittent problem, depending on environmental conditions.

Minnesota and North Dakota produce 580,000 acres of dry beans. In a given year, approximately 1 to 20 percent of this acreage is treated with fungicides. Eighty percent of the bean crop in the treated areas is rotated with small grains. The remainder is rotated to either potatoes under irrigation or occasionally to sugar beets.

In the Colorado area there are approximately 150,000 acres that are affected by foliar pathogens; 60 percent of this area is treated with fungicides. Of the treated area approximately 50 percent is rotated with sugar beets, sunflowers, small grains, or miscellaneous vegetables that do not appear on the chlorothalonil label. The other 50 percent is rotated with corn.

If rotational restrictions are followed and different acreage is treated each year, and if this information is correct, 80 percent of the fungicide-treated bean acreage in Minnesota and North Dakota and 50 percent of the treated acreage in the Colorado region could be affected by these restrictions at some point in time.

12. *Comment on grapes.* The EBDC/ETU Task Force submitted information and documentation supporting the continued use of EBDCs on grapes. The Task Force highlighted several issues that they considered important for the use of EBDCs on grapes including: (a) The Agency incorrectly stated that EBDCs are not registered for control of eutypa dieback and are efficacious against both phomopsis cane and leaf spot and eutypa dieback; (b) EBDCs are the only efficacious material for control of black rot and downy mildew, specifically in the eastern United States; (c) Mancozeb is used to control angular leaf scorch in New York; and (d) There have been reports of captan-treated grapes not being accepted by grape processors.

Response. Deadarm is listed on the mancozeb label as one of the diseases the fungicide controls. However, scientists now classify deadarm as 2 distinct diseases: (1) eutypa dieback and (2) phomopsis cane and leaf spot. The Agency maintains that mancozeb is only efficacious against one of the 2 diseases once grouped together as deadarm—phomopsis cane and leaf spot.

The Agency maintains that black rot can be controlled effectively with either myclobutanil or triadimefon if EBDCs are cancelled on grapes.

Downy mildew could be controlled by either captan or copper fungicides in the absence of EBDCs. However, assuming the information available to the Agency is correct, copper fungicides are phytotoxic to hybrid grapes, possibly resulting in a 20 percent yield loss on approximately 10 percent of the hybrid grape acreage.

Angular leaf scorch is a new fungal disease not listed on the mancozeb label. Mancozeb is used to control the fungus reported to occur on approximately 5 to 10 percent of the grape acreage in New York.

The Agency is aware of this new disease in New York, but it does not have data to determine the economic loss if EBDCs were no longer available to control angular leaf scorch. The Agency is also aware that there have been reports of grape processors refusing to accept grapes treated with captan and has included this information in the final benefits analysis for EBDCs on grapes.

13. *Comment on lettuce.* EAK AG, Inc. (on behalf of the Grower-Shipper Vegetable Association of Central California and the Western Growers Association) and other commenters submitted information and documentation supporting the continued use of EBDCs on lettuce. The material included data on the comparative efficacy of registered fungicides on lettuce, production information, usage information, and proposed label changes.

Response. The information provided by the commenters was considered in the final benefits assessment for the use of EBDCs on lettuce.

14. *Comments on leafy greens.* Comments were received from leafy greens growers, food processors, and university extension scientists supporting the continued use of maneb on leafy greens. One processor submitted as comments to the Agency a paper to be published in the journal "Plant Disease" studying the effectiveness of maneb to control leafspot on turnip leafy greens.

Response. The Agency is aware of the importance of maneb for control of foliar diseases on leafy greens. Data submitted by Southern Frozen Foods indicating the effectiveness of EBDCs for control of leafspot on turnip greens helped the Agency to estimate yield losses on that crop in the absence of EEDCs. The Agency encourages the public to submit scientific, statistically sound studies for comparative performance purposes. Data provided by other commenters were used in estimating yields and crop values.

15. *Comments on onions.* Growers from New York state submitted comments supporting the continued use of EBDCs on onions. One commenter stated that EBDC fungicides are applied and used according to Cornell University Cooperative Extension Service recommendations. The fungicides are alternated weekly so that pesticide resistance is minimized. EBDC fungicides are relatively inexpensive when compared to alternative materials, and are a major component in overall disease management programs. Another grower commented that EBDCs provide outstanding control of onion diseases; therefore, growers can use fewer sprays.

The American Dehydrated Onion and Garlic Association also submitted comments supporting the continued use of EBDCs on onions. In the PD 2/3, EPA assumed that metalaxyl would replace 33 percent of the EBDC-treated acres if the EBDCs were no longer available and iprodione would replace another 33 percent. The commenter states that metalaxyl use will be less than 33 percent and iprodione use greater than 33 percent.

Response. The relative expense of the EBDC fungicides, and their role in overall disease management in onions, are addressed in the PD 2/3 and in this Final Determination.

In the PD 2/3 the Agency concluded that in the event of a cancellation, one-third of the onion acres currently treated with EBDCs would be treated with chlorothalonil, one-third would be treated with chlorothalonil plus metalaxyl, and one-third would be treated with iprodione. While the above assumption of each of the 3 alternative scenarios replacing one-third of EBDC treatments may not be precise, the Agency has no data to support other assumptions.

16. *Comment on papayas.* The Hawaiian Papaya Industry Association submitted information and data indicating that chlorothalonil is less efficacious than mancozeb for control of phytophthora fruit rot of papaya. The commenters stated that applications of chlorothalonil result in a 6 percent yield loss (a decrease of 2,085 pounds of papaya per acre) compared to applications of mancozeb.

Also, the commenter indicated that quarantine regulations require Hawaiian papaya fruit to be treated to reduce the introduction of fruit flies into the continental United States. Previously, papaya fruit were treated with a double hot water dip. This year, the industry began a vapor and dry heat treatment to increase pulp temperatures beyond those obtained with the double hot water treatment. In one study submitted by the commenters, chlorothalonil-treated papaya fruit followed by

applications of the double hot water treatment bath resulted in approximately 85.8 percent of the fruit scalded (i.e., browning of papaya fruit) on at least 10 percent of the surface area. Similar results are expected with the vapor/dry heat method.

Response. The Agency agrees that chlorothalonil appears to be less efficacious than mancozeb for control of phytophthora fruit rot on papayas. This information was included in the benefits assessment described in this document.

The Agency acknowledges that scalding of chlorothalonil-treated fruit followed by either a vapor/dry heat or double hot water treatment is of serious concern for Hawaiian papaya growers. Because of this, the Agency does not currently consider chlorothalonil as a viable alternative for Hawaiian papaya growers. This information was included in the current benefits analysis.

17. *Comments on pears.* Comments were received from pear growers and university extension agents supporting the continued use of EBDCs on pears. The commenters stated that EBDCs are effective in controlling pear scab and fabrea leaf spot on pears.

Response. The Agency is aware that mancozeb is an effective fungicide for control of fabrea leaf spot and pear scab. The Agency believes that in the absence of EBDCs, pear growers could use ziram without a decrease in efficacy.

18. *Comments on peppers.* Comments were received from pepper growers, State agricultural agencies, and other interested parties supporting the continued use of EBDCs on peppers. The commenters stressed the importance of EBDCs used in combination with copper for control of bacterial spot. They stated that copper compounds are the only registered pesticide to control bacterial spot but are not effective alone against the disease due to the development of bacterial spot resistance to copper compounds.

Response. The Agency acknowledges that EBDCs enhance the ability of copper compounds to control bacterial spot. Copper compounds, the only registered pesticide for control of bacterial spot, does not appear to be efficacious by itself to control the disease. This information was considered in the final benefits analysis for the use of EBDCs on peppers.

19. *Comments on peanuts.* The EBDC/ETU Task Force submitted information and documentation supporting the continued use of EBDCs on peanuts. The Task Force presented 3 issues: (a) Chlorothalonil, the registered alternative to EBDCs on peanuts, promotes an increase in Sclerotinia blight infection; (b) Crop rotation restrictions with chlorothalonil need to be considered. The chlorothalonil label states that fields treated with chlorothalonil cannot be rotated to crops that are not on the label for 12 months after a chlorothalonil application; and (c) EBDCs provide a supplemental source of manganese for North Carolina and Virginia peanut growers. The Task Force indicated that North Carolina and Virginia peanut soils are commonly deficient in manganese. Growers in these areas commonly apply mancozeb for disease control and as a source of supplemental manganese. If EBDCs are unavailable on peanuts, the EBDC/ETU Task Force stated that growers would apply 1 to 2 applications of chelated manganese per growing season.

Response. From a review of the data included in the Task Force's comments, the Agency agrees that applications of chlorothalonil could promote an increase in the incidence of Sclerotinia blight infection compared to untreated fields. The Agency estimates that 1 to 2 additional iprodione or pentachloronitrobenzene applications would be needed (to control an increase in Sclerotinia blight infection).

The Agency is aware that peanut growers in the North Carolina/Virginia peanut growing region and the southeastern peanut growing region commonly rotate their crop. However, the Agency was not provided with information as to the affected acreage or the affected practices in these areas and therefore cannot estimate the impact.

The Agency recognizes that some growers in North Carolina and Virginia rely on mancozeb as a manganese source and estimates that 1 to 2 additional chelated manganese micronutrient applications might be necessary in these 2 States if EBDCs were not available on peanuts.

20. *Comments on the importance of EBDCs and TPTH to potato cultivation.* The Agency received comments from potato growers and university extension plant pathologists discussing the importance of mancozeb used in combination with TPTH, a registered fungicide for control of early and late blight on potatoes. The commenters stated that TPTH is phytotoxic to the crop at the label rate. Growers commonly tank-mix a reduced rate of TPTH with mancozeb to avoid phytotoxicity and still have efficacious control of potato diseases. The commenters contend that without the use of mancozeb, TPTH could not be used effectively.

Response. The Agency acknowledges that TPTH phytotoxicity on potatoes is of serious concern, especially in the New England and the North Central potato growing regions. TPTH applied at a reduced rate in combination with mancozeb is efficacious against both early and late blight without a resulting phytotoxic response. If the use of EBDCs is cancelled on potatoes, and if the information is correct, growers in these regions will not be able to use TPTH effectively. This information was included in the benefits assessment for the use of EBDCs on potatoes.

21. *Comments on the importance of EBDCs in controlling late blight on potatoes.* Several commenters discussed the importance of EBDCs for control of late blight and stated that Ridomil® MZ58, a fungicide containing mancozeb and metalaxyl, is used to control the fungus on potatoes. The commenters stated that if EBDCs are cancelled, Ridomil® MZ58 would not be available for disease control. Another metalaxyl product, Ridomil®/Bravo® 81W is also available for late blight control. Ridomil®/Bravo® 81W contains chlorothalonil and metalaxyl as its 2 active ingredients. The commenters indicated that due to crop rotation restrictions with chlorothalonil, growers that intend to rotate crops not listed on the chlorothalonil label would not be able to use Ridomil®/Bravo® MZ58.

Response. The Agency agrees that late blight is a serious disease on potatoes, especially in New England, and to a lesser extent, in Florida, New York, Pennsylvania, and Wisconsin. Without the use of EBDCs, growers would switch to chlorothalonil and metalaxyl for control of late blight. However, crop rotations with potatoes would be limited to crops listed on the chlorothalonil label. If growers have a history of late blight, then growers would have to alter their crop rotation practices to allow the use of Ridomil®/Bravo® 81W on their fields.

22. *Comments on chlorothalonil as an alternative fungicide for potatoes.* Commenters disagreed with the Agency's conclusion that chlorothalonil statistically is more effective than mancozeb in controlling early and late blight on potatoes. The commenters stated that although research has shown chlorothalonil is more efficacious than mancozeb, specifically for early blight control, the differences are not statistically significant.

Other commenters including the EBDC/ETU Task Force, the National Potato Council, and State extension agents disputed the viability of chlorothalonil as an alternative to EBDCs on potatoes. These commenters all stated that crops treated with chlorothalonil cannot be rotated with crops that are not on the chlorothalonil

label within 1 year after the last application. The commenters stated that the restrictions will interfere with crop rotations practiced by U.S. potato growers.

Response. In the PD 2/3, the Agency concluded that if EBDCs are cancelled on potatoes, growers would switch to chlorothalonil. At that time, Agency scientists concluded that chlorothalonil-treated acreage would have higher yields than those treated with mancozeb. However, after reviewing comparative performance literature on the 2 fungicides used for the PD 2/3 and new data submitted as comments to the PD 2/3, the Agency agrees that there are no significant differences between the fungicides for control of early blight. The Agency considered this information in its PD 4 benefits analysis.

The Agency is aware that chlorothalonil has crop rotation restrictions. However, according to data submitted by commenters, growers can use anilazine (an alternative fungicide that does not have these restrictions), without a decrease in efficacy for control of early blight. Anilazine's higher cost has been factored into the Agency's analysis.

Fungal resistance to metalaxyl has limited the use of the fungicide for control of late blight, a potentially devastating disease to potato producers. Due to the limited mode of action of metalaxyl, plant pathogenic fungi have developed resistance to the fungicide. This has prompted the registrant of metalaxyl to package the fungicide with protectant fungicides having a broader mode of action (e.g., chlorothalonil or EBDCs). The use of metalaxyl and a protectant fungicide results in a decrease in the development of fungi resistant to metalaxyl. Without EBDCs, growers whose crop rotations limit their use of chlorothalonil would not be able to apply metalaxyl. This would leave the growers without an efficacious fungicide for control of late blight. The Agency has considered this situation in the final benefits analysis.

23. *Comment on resistance to alternative fungicides for potatoes.* A North Dakota State University researcher stated that there have been reports of fungal resistance to thiabendazole and TM by the silver scarf fungus, a fungus associated with potato seed-piece decay.

Response. The Agency agrees that, if this information is correct, silver scarf resistance to thiabendazole and TM may threaten the usefulness of these fungicides in the future. However, even if EBDCs are not available, captan could be used effectively to prevent potato seed-piece decay.

24. *Comment on small grains.* The EBDC/ETU Task Force submitted information and documentation supporting the continued use of EBDCs on small grains. The Task Force stated that crown rust infection on oats has been increasing in North Dakota and Wisconsin. The commenters argued that without the use of EBDCs, there would be no efficacious fungicides to control the disease on oats. The Task Force also noted that triadimefon, a likely alternative to EBDCs on small grains, has crop rotation restrictions.

Response. The Agency acknowledges that without the use of EBDCs, oat growers would have no efficacious fungicide for control of crown rust and could have yield losses as high as 20 percent, if the information presented is correct. The Agency is also aware of crop rotation restrictions with triadimefon. This information was included in the benefits analysis of EBDCs on small grains.

25. *Comments on spinach.* Commenters in support of the use of EBDCs on spinach stated their opinion that: (a) Maneb provides excellent control of spinach downy mildew at a per acre cost of only $14.50 compared to a per acre application cost of $83.31 for fosetyl-aluminum; (b) Spinach yields were reduced by 23 to 30 percent without applications of maneb; and (c) Fosetyl-aluminum has proven to be inconsistent in combating downy mildew.

Response. The Agency agrees that maneb is less expensive and more effective than fosetyl-aluminum for control of downy mildew on spinach. Fosetyl-aluminum is not registered for use on spinach but has been used on spinach under FIFRA section 18. This information was included in the final benefits analysis for spinach. On the basis of data and other information, the Agency has also revised its benefits assessment for spinach and now estimates that yield losses of up to 40 percent for the winter crop in certain areas are likely if viable alternatives are not available and if the disease situation is severe. Further, the Agency believes that an aggregate yield loss is likely without effective controls.

26. *Comment on sweet corn.* The EBDC/ETU Task Force submitted comments supporting the continued use of EBDCs on sweet corn. Comments were provided concerning the economics of fungicide costs for fresh market sweet corn for EBDCs and alternatives and resulting impacts on production.

Response. The Agency has taken into account new cost information. The economics assessment for sweet corn has been revised to reflect new chemical cost and revenue figures.

27. *Comment on the importance of EBDCs in controlling late blight on tomatoes.* The California Tomato Board and the Processed Tomato Foundation submitted information and documentation discussing the importance of mancozeb used in combination with metalaxyl for control of late blight on tomatoes in California. Due to reports of fungal resistance to the systemic fungicide metalaxyl, the fungicide is sold as a package mixture containing metalaxyl in combination with a protectant fungicide (chlorothalonil or mancozeb) to reduce the development of fungal resistance to metalaxyl. Without the continued registration of mancozeb on tomatoes, the commenters expressed concern that the registrants for metalaxyl may discontinue supporting the use of metalaxyl on tomatoes.

Response. The Agency agrees that in the absence of EBDCs for tomatoes, the continued use of metalaxyl may be limited. Metalaxyl is only marketed with mancozeb or chlorothalonil. Thus, the use of metalaxyl would be limited as a result of the chlorothalonil plant back restriction. The combination of metalaxyl and EBDCs provides a level of control of late blight on tomatoes that cannot be achieved in the long term by either chemical alone. However, growers may also choose anilazine. Thus, growers in California could use metalaxyl as a package mix with chlorothalonil or anilazine alone for control of late blight without a decrease in efficacy. Crop rotation restrictions are not listed on the anilazine label. However, crop rotation restrictions with chlorothalonil may limit the metalaxyl/chlorothalonil combination for tomato growers.

28. *Comment on the importance of EBDCs in controlling bacterial diseases on tomatoes.* Comments relating to the EBDC PD 2/3 were received from the EBDC/ETU Task Force, tomato growers, user groups, university researchers, and other interested parties discussing the role of EBDCs for the control of bacterial diseases on tomatoes. The commenters stated that the Agency failed to include in its analysis consideration of the use of EBDCs and copper to control bacterial spot. Growers commonly tank-mix copper and EBDCs and claim it is the only efficacious material for bacterial disease control.

Response. For the PD 2/3 analysis, the Agency did not consider the use of EBDCs for control of bacterial diseases on tomatoes. EBDC labels do not list bacterial diseases as one of the pests

the pesticide controls. Thus, the Agency was not aware of a common grower practice of mixing copper and maneb for bacterial disease control on tomatoes. The Agency agrees that applications of EBDCs and copper are efficacious against bacterial diseases and even against populations of bacteria resistant to copper. However, studies have shown that there is no significant difference between applications of chlorothalonil/copper and EBDC/copper for control of copper sensitive bacterial spot. In situations where insensitive isolates are present, chlorothalonil may not be effective. The Agency has data indicating that this could result in yield losses as high as 20 percent to affected tomato growers. This information was considered in the final benefits assessment for the use of EBDCs on tomatoes.

29. *Comment on chlorothalonil as an alternative fungicide for tomatoes.* The Processed Tomato Foundation submitted comments discussing the use of chlorothalonil as an alternative fungicide for California tomato growers. The Processed Tomato Foundation included information and data disagreeing with the Agency's conclusion that chlorothalonil is more efficacious than EBDCs for control of black mold. They concluded that there are no differences in efficacy between the 2 fungicides. The grower group also stated that chlorothalonil is unsuitable for California tomato growers due to crop rotation restrictions on the chlorothalonil label. Fields treated with chlorothalonil cannot be rotated with crops not listed on the chlorothalonil label.

Response. From a review of the data submitted by the Processed Tomato Foundation, the Agency agrees that there is no difference in efficacy between chlorothalonil and EBDCs for control of black mold. This new information was included in the final benefits assessment.

The Agency is aware that crop rotation restrictions on the chlorothalonil label may interfere with crop rotations practiced by California tomato growers. However, data were not submitted by the commenters for the Agency to determine what typical crop rotations are commonly practiced on the affected acres. Without these data, the Agency cannot determine what the economic impact of crop rotation restrictions will be to California tomato growers. If growers choose to rotate their tomato fields with crops not listed on the chlorothalonil label, California growers could switch to anilazine without a decrease in efficacy or similar rotational considerations. However, producers would incur an increased cost due to the higher price of anilazine.

30. *Comment on tomato usage surveys.* Pesticide usage surveys on tomatoes were submitted by The California Tomato Growers Association.

Response. The Agency appreciates the information from the California Tomato Growers Association survey. This information helped the Agency to have a better understanding of chemical usage on tomatoes and was considered in the final benefits analysis for tomatoes.

E. Summary

The estimated total benefits for this Final Determination compared to the benefits estimated in the Preliminary Determination are summarized in the following Table 3:

TABLE 3.—ESTIMATED TOTAL BENEFITS OF EBDCS FOR PD 2/3 AND PD 4.

Food crop	Estimated PD 2/3 benefits[1]	Estimated PD 4 benefits[2]	Reason for changes in benefits
Apples	$0.3 -$10.3 million total impacts.	Estimate a $16.7 to $51.8 million loss to society. This represents about 0.5% of U.S. value of production..	(1) Additional captan applications on eastern apple acreage for control of apple diseases. (2) Additional miticide applications on eastern apple acreage due to incompatibility of mineral oil and captan. (3) Additional zinc sprays on northeast apple acreage.
Almonds	Not enough data to quantify; potential impacts expected..	Not enough data to quantify; potential impacts expected..	
Apricot	Not enough data to quantify; minimal impact expected..	Not enough data to quantify; potential impacts expected..	
Asparagus	Not enough data to quantify; potential impacts expected..	Not enough data to quantify; potential impacts expected..	
Bananas	$0.3 million total impacts.	Estimate a $2 to $5 million total producer impact. This represents about 42% of Hawaii and Puerto Rico value of production..	Lack of efficacious registered alternative fungicides for Hawaiian or Puerto Rican banana growers.
Barley	$0.3 to $2.1 million total impacts.	Estimate $0.33 to $1.9 millon impact. This represents about 0.04 to 0.2% of U.S. value of production..	
Beans, dry	Not separated from succulent beans.	Estimate $0.5 to $1.6 million impact. This represents about 0.3% of U.S. value of production..	Crop rotation restrictions with chlorothalonil.
Beans, lima	$0.7 million total impacts.	Estimate $0.5 million impact.	(1) The price of chlorothalonil has decreasoil. (2) Crop rotation restrictions with chlorothalonil.
Beans, succulent	$1.9 to $2.1 million total impacts.	Estimate $1.3 to $1.4 million impact. This represents about 0.9% of U.S. value of production..	The price of chlorothalonil has decreased.
Broccoli	No impact expected.	No impact expected.	
Brussels sprouts	No impact expected.	No impact expected.	
Cabbage	No impact expected.	No impact expected.	

TABLE 3.—ESTIMATED TOTAL BENEFITS OF EBDCs FOR PD 2/3 AND PD 4.—Continued

Food crop	Estimated PD 2/3 benefits[1]	Estimated PD 4 benefits[2]	Reason for changes in benefits
Caprifigs	Not enough data to quantify; potential impacts expected..	Not enough data to quantify; potential impacts expected..	
Carrots	$0.13 million total impacts.	Estimate $1.2 million total impacts. This represents less than 1% of the U.S. value of production..	(1) Revised percent-crop treated data due to better usage information. (2) More accurate estimates for fungicide application rates and frequencies on a statewide basis.
Cauliflower	No impact expected.	No impact expected.	
Celery	$1.3 to $3.4 million efficiency impacts.	Estimate $1.3 to $3.4 million total impact to society. This represents about 1.3% of U.S. value of production..	
Collards	Not enough data to quantify; potential impacts expected..	Estimate $5.7 to $13.7 million total impacts to producers for collards (total greens crop value in the primary state (GA) is $48 million) ..	Lack of viable fungicide to control leafspot diseases.
Corn, field (seed)	Not enough data to quantify.	Estimate $1 to $1.5 million total impact to society. This represents less than 2% of the U.S. value of production..	Crop rotation restrictions with chlorothalonil.
Corn, sweet	$2.1 to $2.5 million total impacts.	Estimate $2.1 to $8.6 million total impact. This represents about 1.8% of the U.S. value of production..	(1) Revised percent-crop treated information due to better usage information. (2) More accurate estimates for fungicide application rates and frequencies on a statewide basis.
Cotton	Not enough data to quantify; no impacts expected..	Estimate $27.2 million producer impact. This represents about 0.7% of U.S. value of production..	Lack of viable fungicide to control cotton rust in southwestern cotton growing region.
Crabapple and quince	Not enough data to quantify; no impacts expected..	Not enough data to quantify; potential impacts expected..	
Cranberry	$0.1 million producer impacts.	Estimate $70,000 producer impacts. This represents about 0.05% of U.S. value of production..	
Cucumbers	$4.0 to $4.9 million producer impacts.	Estimate $1.4 to $6.1 million producer impact. This represents about 1 to 4% of the U.S. value of production. Impacts for the western U.S. could not be quantified..	(1) Revised percent-crop treated data due to better usage information. (2) More accurate estimates for fungicide application rates and frequencies on a statewide basis.
Eggplant	Not enough data to quantify; potential impacts expected..	Not enough data to quantify; potential impacts expected..	
Endive	Not enough data to quantify; potential impacts expected..	Not enough data to quantify; potential impacts expected..	
Fennel	Not enough data to quantify; no impacts expected..	Not enough data to quantify; potential impacts expected..	
Grapes	$1 to $3 million total impacts.	Estimate $1.8 to $17.5 million impact to society. This represents 0.1 to 1.2% of U.S. value of production..	(1) Reports of grape processors refusing to accept captan-treated fruit. (2) New grape disease reported in New York controlled by EBDCs.
Kale	Not enough data to quantify; impacts expected..	Estimate $2.1 to $5.0 million total impacts to producers for kale..	Lack of viable, registered fungicide to control leafspot diseases.
Kohlrabi	Not enough data to quantify; impacts expected..	Not enough data to quantify; impacts are likely..	
Lettuce	$40 to $204 million efficiency impacts.	Estimate $40 to $204 million impacts. This represents about 4.0 to 20% of U.S. value of production..	
Melons (cantaloupe, casaba, crenshaw, honeydew, and watermelon).	$0.3 million total impacts for cantaloupe, casaba, crenshaw, and honeydew. $0.8 million producer impacts for watermelon..	$0.98 to $4.9 million producer impacts for cantaloupe, casaba melon, crenshaw melon, honeydew, and watermelon combined. This represents less than 1% of U.S. value of production. Impacts for the western U.S. could not be quantified..	Revised percent-crop treated information due to better usage information.
Mustard greens	Not enough data to quantify; impacts expected..	Estimate $4.1 to $9.7 million total impacts to producers for mustard greens, and turnip greens combined..	Lack of viable fungicide to control leafspot diseases.
Nectarines	Negligible rise in impacts.	Estimate $10,000 impact.	
Oats	$0.1 to $0.5 million producer impacts for oats rye..	Estimate $3.8 to $25 million impact. The $25 million represents about 4.5% of the U.S. value of production..	Previously resistant oat varieties now susceptible to crown rust.

TABLE 3.—ESTIMATED TOTAL BENEFITS OF EBDCs FOR PD 2/3 AND PD 4.—Continued

Food crop	Estimated PD 2/3 benefits[1]	Estimated PD 4 benefits[2]	Reason for changes in benefits
Onions	$6.5 million producer impacts.	Estimate $4.2 to $5.5 million impact. This represents about 1% of the U.S. value of production..	(1) Revised percent-crop treated data due to better usage information. (2) More accurate estimates for fungicide application rates and frequencies on a statewide basis.
Papaya	Not enough data to quantify; no impacts expected..	Estimate $0.24 to $7.9 million producer impacts. This represents about 54% of the U.S. value of production..	Scalding (browning of papaya fruit) occurs when chlorothalonil-treated fruit are treated for export from Hawaii.
Peaches	<$15,000 total impacts.	Estimate $10,000 impact.	
Pears	Not enough data to quantify; minimal impacts expected..	Estimate $300,000 impact. This represents less than 1% of the U.S. value of production..	Increase in cost and number of applications of the alternative fungicide ziram.
Peanuts	$2.4 million total impacts.	Estimate $9.1 million producer impacts. This represent about 6% of the U.S. value of production..	(1) Additional fungicide applications are needed to control Sclerotinia blight due to applications of chlorothalonil. (2) Additional manganese applications are needed in North Carolina and Virginia.
Pecan	Not enough data to quantify; minimal impacts expected..	Not enough data to quantify; potential impacts expected..	
Peppers	$49 to $98 million efficiency impacts.	Estimate $80 to $85 million total impact. This represents 33 to 35% of the 1989 U.S. value of production..	(1) Lack of alternatives for control of bacterial spot. (2) More accurate estimates for fungicide application rates and frequencies.
Pineapple	Not enough data to quantify; potential impacts expected..	Not enough data to quantify; potential impacts expected..	
Potatoes	$0.4 million producer impacts.	Estimate $40.4 million total impact. Impacts from chlorothalonil crop rotation restrictions not included in this estimate. The total impact estimate represents about 2% of the U.S. value of production..	(1) Equal efficacy of chlorothalonil and EBDCs. (2) Crop rotation restrictions with chlorothalonil. (3) Use of anilazine as an alternative fungicide to both chlorothalonil or EBDCs for the control of early blight.
Pumpkins	$77,000 total impacts.	Estimate $139,000 to $706,000 impact to eastern pumpkin production. Impacts for the western U.S. could not be quantified (total crop value undetermined) ..	(1) Revised percent-crop treated information due to better usage information. (2) More accurate estimates for fungicide application rates and frequencies on a statewide basis.
Rhubarb	Not enough data to quantify; no impacts expected..	Not enough data to quantify; potential impacts expected..	
Rye	$0.1 to $0.5 million total impacts for oats rye combined..	Estimate $10,000 to $60,000 impact. This represents about 0.03 to 0.2% of the U.S. value of production..	
Spinach	$19 to $27.5 million total impacts.	Estimate $5 to $27.5 million producer impact. This represents about 50% of the U.S. value of production..	More accurate estimates for fungicide application rates and usage.
Squash	$3.4 to $4.8 million total impacts.	Estimate $271,000 to $810,000 total impacts to eastern squash production. This figure represents less than 1% of the U.S. value of production. Impacts for the western U.S. could not be quantified..	(1) The price of chlorothalonil has decreased. (2) More accurate estimates for application rates and frequencies. (3) Refined projections for the areas of impacts.
Sugar beet	Not enough data to quantify; potential impacts expected..	Not enough data to quantify; potential impacts expected..	
Tomatoes	$0.1 million total impacts.	Estimate $32 to $45 million impacts. This represents about 3% of the U.S. value of production..	(1) Crop rotation restrictions for the use of chlorothalonil on California tomato acreage. (2) Possible lack of control of bacterial leaf spot. (3) Decrease in efficacy for control of bacterial speck. (4) Equal efficacy between anilazine, chlorothalonil, and EBDCs for control of black mold.
Turnip greens	Not enough data to quantify; impacts expected..	Estimate $3.2 to $7.6 million total impacts to society for turnip greens..	Lack viable fungicide to control leafspot diseases.

TABLE 3.—ESTIMATED TOTAL BENEFITS OF EBDCs FOR PD 2/3 AND PD 4.—Continued

Food crop	Estimated PD 2/3 benefits[1]	Estimated PD 4 benefits[2]	Reason for changes in benefits
Wheat	$1.6 to $11.7 million total impacts.	Estimate $1.7 to $10 million impact. This represents about 0.03 to 0.1% of U.S. value production..	
Commercial Ornamentals	Impacts expected.	Estimate $315,000 impact.	
Turfgrass	$14,000 total impact.	Estimate $10,000 impact.	

[1]Total Benefits = producer revenue impacts + producer cost impacts + consumer impacts.
[2]If only producer impacts are given, then the Agency was not able to adequately quantify consumer impact estimates for the given site. Potential consumer impacts may occur.

VI. Comments of the Scientific Advisory Panel, Secretary of Agriculture and Other Parties

As required under sections 6 and 25 of FIFRA, the Agency provided its Preliminary Notice of Determination and Technical Support Document to the Scientific Advisory Panel and the Secretary of Agriculture, respectively, for their comments, which are presented below.

A. Comments of the Scientific Advisory Panel -May 15, 1990

EPA presented its preliminary determination on the EBDCs at a public meeting of the Scientific Advisory Panel held in Arlington, Virginia on May 15, 1990. The Panel issued its response in a written report of May 31, 1990. The Panel's report is reproduced below in its entirety:

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel –A Set of Scientific Issues Being Considered by the Agency in Connection with the Special Review of Ethylene Bisdithiocarbamate (EBDC) Pesticides Including Ethylene Thiourea (ETU) as a Category B_2 Carcinogen.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) reviewed a set of scientific issues considered by the Environmental Protection Agency (EPA) in connection with the Special Review of Ethylene Bisdithiocarbamate (EBDC) pesticides including Ethylene Thiourea (ETU) as a Category B_2 Carcinogen. The review was conducted in an open meeting held in Arlington, Virginia, on May 15, 1990. Panel members present for the review were Dr. James Tiedje, Dr. Robert Anthony, Dr. Edward Bresnick, Dr. Mont Juchau, Dr. Peter Magee, and Dr. John Wilson. In addition, Dr. Charles Capen of Ohio State University and Dr. Ernest McConnell of Raleigh, NC served as Special Government Employees, and Dr. Richard Griesemer of the National Institute of Environmental Health Sciences served as an Agency representative on the Panel.

Public notice of the meeting was published in the Federal Register on April 13, 1990 (55 FR 13951).

Oral Statements were received from (1) the EBDC/ETU Task Force comprised of: Dr. Robert H. Larkin (E.I. DuPont de Nemours & Company), Dr. Kenny S. Crump (Clement Associates, Inc.), Dr. W. Gary Flamm (Science Regulatory Services International), and Drs. Harvey E. Scribner and Ping Kwong (Peter) Chan (Rohm and Haas Co.); (2) Derl I. Derr (International Apple Institute); (3) Dr. John Simons (JMS Flower Farms, Inc.); (4) Ron Walker (National Potato Council); and (5) Dr. James Wilson (American Industrial Health Council).

In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency, the Panel unanimously submits the following report.

Report of Panel Recommendations
General Comments

1The Panel wishes to acknowledge and commend the Agency for the fine manner in which the content of the reports was assembled and for the clear organization of its presentations.

Issue No. 1. Does the Panel agree with the Agency's intent to use the results of the EBDC/ETU Market Basket Survey as a primary basis for its dietary risk assessment in the EBDC PD 4; and with the Agency's intent to use the dietary exposure assessment described in the PD 2/3 for those crops for which market basket data or other appropriate data are not submitted?

Panel response. The Panel supports the Agency's intent to use the results of the EBDC/ETU Market Basket Survey as a primary basis for its dietary risk assessment in the EBDC PD 4. The Panel also supports the intent to use the dietary exposure assessment described in the PD 2/3 for those crops for which market basket data or other appropriate data are not submitted. The Panel reminds the Agency, however, that market basket survey data for this purpose can only be interpreted if the chemical use pattern on each crop surveyed has not changed, or if it has changed, it can be estimated. Both the EPA and the registrants involved appear to support these intents; no serious objections have been raised to date. However, the Panel encourages further refinement of the methodology described, particularly as such refinements would relate to considerations in selection of products for testing, more reliable estimates for processing losses, and other losses that occur between the market basket and the dinner table.

Issue No. 2. Does the Panel agree with the Agency's intent to use the average residue levels, rather than 95th percentile or maximum residues from the EBDC/ETU Market Basket Survey in its carcinogenic dietary risk assessment for the EBDC PD 4?

Panel response. It is the Agency's intent to use average residue levels as a general rule, the Panel believes that the use of dietary residue levels for dietary risk assessment calculations should be comparable to the health effect which is of concern. The use of average residue levels may be appropriate for chemicals whose effect is the result of repeated or chronic exposures (i.e., chronic nephritis, organ weight changes, cancer, etc.). Conversely, for chemicals which elicit significant acute effects (i.e., cholinesterase inhibition, developmental effects, etc.), use of 95th percentile or higher estimates of residue levels may be warranted.

The Panel is concerned that groundwater exposure information seems to be lagging significantly behind the dietary exposure and yet it's not clear that exposure in drinking water should be substantially less than from diet since leaching of this compound is known.

In view of the high toxicity of EBDC compounds to aquatic organisms, and the potential effects on reproduction in birds, the Panel urges the Agency to thoroughly investigate the potential ecological effects of EBDC compounds and ETU in aquatic and terrestrial systems, including their environmental fate, acute and chronic effects, if any, on aquatic and terrestrial organisms, and the potential for secondary poisoning in predatory or scavenging animals.

Issue No. 3. Based upon the Agency's Cancer Assessment Guidelines of 1986, does the Panel agree with the weight of evidence evaluation and carcinogenic classification of ETU for this data set?

Panel response. The Panel agrees with the classification of the EBDC's (and ETU) as a Class B_2 carcinogen. This conclusion is based upon (a) the appearance of both adenomas and carcinomas in two species, the mouse (2 strains) and the rat, (b) the appearance of tumors in two different tissues (not in the same animal), i.e., in liver of the mouse and in the thyroid of the rat, and (c) the increasing incidence of carcinomas, both in the liver and thyroid of the mouse and rat, respectively, in a dose dependent manner. The Panel believes that the Agency's approach to calculating the Q_1^* using the high dose-mouse liver tumor data is appropriate, i.e., discarding these results to better fit a model would be inappropriate. However, the Panel recommends that Q_1^* calculations be conducted with data obtained from the different tumor model systems where available and the values be compared. Specifically, a Q_1^* should be calculated using

the thyroid tumor data in the rat as well as the liver tumor results in the mouse.

The Agency should make use of all available relevant data in its risk extrapolations to humans. The relevance of high dose mouse liver data compared to low dose level risk extrapolations must be carefully evaluated in the perinatal paradigm recently submitted to the Agency by the National Toxicology Program (NTP).

The Panel has evaluated the information on the potential genotoxicity of the EBDC's and ETU. The Panel concluded that the evidence for genotoxicity was equivocal both in prokaryotic and eukaryotic test systems.

Issue No. 4. Do the current EPA Cancer Risk Assessment Guidelines adequately provide for classification of chemical carcinogens such as ETU? If not, does the Panel have any specific comments which would assist the Agency in categorizing the carcinogenic effects of ETU?

Panel response. Current EPA Cancer Risk Assessment Guidelines (51 FR 33992–34054, September 24, 1986) provide for the use of all relevant supportive information in the evaluation of the overall weight of evidence, including physiological, biochemical, and toxicological observations. While the "guidelines" recommend the use of other "relevant supportive information" in the carcinogenic classification of a particular chemical, the Agency is encouraged to better use all available evidence in its final determination. For example, the guidelines make several references to hormonal function in interpreting the carcinogenic event(s):

Toxicologic effects other than carcinogenicity [e.g., suppression of the immune system, endocrine disturbances, organ damage) that are relevant to the evaluation of carcinogenicity should be summarized. (pg. 33994) The carcinogenic effects of agents may be influenced by non-physiological responses [such as extensive organ damage, radical disruption of hormonal function, ...) induced in the model systems. (pg. 33995)

Interpretation of animal studies is aided by the review of target organ toxicity and other effects (e.g., changes in the immune and endocrine systems) that may be noted in prechronic or other toxicologic studies. (pg. 33995)

Such evidence, where available, should be incorporated to the fullest extent possible in the Agency's weight-of-the-evidence evaluation and carcinogenic classification. A more thoughtful use of such data by the Agency, as broadly interpreted in the guidelines, would permit a more flexible approach to carcinogenic classifications.

Although the cancer risk assessment guidelines accommodate the consideration of hormonal effects in the etiology of certain cancer responses, the incorporation of such approaches in the Agency's cancer risk assessment of EBDC/ETU should be scrutinized carefully and weighed against the present method(s) of risk extrapolation.

Issue No. 5. Considering the available biological evidence on ETU, does the Panel believe the evidence is indicative of a threshold response or a non-threshold response for thyroid tumors? Does the Panel have any specific comments regarding the mechanisms for the carcinogenic effects observed in the rodent bioassay for ETU with regard to threshold versus non-threshold phenomena for the thyroid?

Panel response. Ethylene Thiourea is a potent goitrogenic compound that at high doses causes profound disruption in thyroid hormone economy and marked elevations in serum thyroid stimulating hormone (TSH). When administered over the lifetime to a highly sensitive species, such as the laboratory rat, the sustained stimulation appears to promote an increased incidence of thyroid follicular cell tumors by a secondary (indirect) mechanism that the evidence suggests is mediated by TSH. A similar increased incidence of thyroid tumors also has been reported in laboratory rats following physiologic perturbations (iodine deficiency or partial thyroidectomy) in the complete absence of xenobiotics. With some other chemicals that induce thyroid tumors by a disruption of endocrine function the proliferative response of follicular cells is abrogated by the exogenous administration of thyroid hormone (usually thyroxine). Doses of the chemical that fail to disrupt thyroid hormone economy and increase TSH are not associated with the development of thyroid tumors under the conditions of the studies. The promoting effects of ETU could be investigated further using an initiation-promotion model such as the one developed by Hiasa, et al. (Carcinogenesis 3:1187, 1982). Studies could also be designed to demonstrate a threshold effect of the chemical and to learn whether exogenous thyroxine will block the development of thyroid tumors.

The correlation between the development of thyroid tumors in rats and liver tumors in the mouse is uncertain. It is the Panel's determination that there are insufficient data to suggest a threshold response in the mouse following administration of ETU.

Issue No. 6. Does the Panel have any specific comments regarding thyroid/pituitary mechanisms where there is experimental animal evidence that multiple organs are involved in the manifestation of tumors, specifically thyroid and liver neoplasia, particularly at doses where there is clear evidence of a radical disruption of hormonal function?

Panel response. The Panel believes that the EBDCs and/or ETU significantly inhibited thyroid peroxidase, decreasing the production of tetraiodothyronine (T_4) and triiodothyronine (T_3). The thyroid hormones (primarily T_3) would ordinarily inhibit, by a negative feedback mechanism, anterior pituitary elaboration of thyrotropin (TSH), which is responsible for the stimulation of thyroid cells to produce more thyroid hormone. In the absence of normal blood levels of thyroid hormones as a result of inhibition of the peroxidase, TSH levels remain elevated and compensatory thyroid follicular cell hypertrophy and hyperplasia result. The Panel believes that a clonal expansion of an initiated cell(s), under the influence of a sustained elevation in TSH, subsequently gives rise to the increased incidence of follicular cell adenomas and carcinomas in the thyroid. However, the Panel was unable to formulate a plausible explanation for the formation of liver tumors as a result of elevated levels of TSH or decreased circulating levels of thyroid hormones.

Issue No. 7. Are the rat and/or mouse appropriate animal models for studying thyroid inhibiting chemical agents with regard to thyroid neoplasia and their predictability for man? How can such laboratory animals be maximized to evaluate the effects of thyroid inhibiting compounds and their relation to a similar response in humans?

Panel response. Because of their small size and short life spans, rats, mice and other rodents are virtually the only species that are used for carcinogenicity bioassay. If a chemical is found to induce thyroid tumors it may prove to have antithyroid activity with simulation of TSH production. In such cases, further studies with the compound in other species may prove valuable in elucidating mechanisms and in investigating extrapolation to man. ETU is such a chemical. The mouse, rat and rabbit demonstrate changes of interest in certain organs (thyroid, liver, pituitary). The chemical in question exerts a pharmacologic action in animals, which is similar to analogs (PTU) in man. Epidemiologic studies from man are valuable but delay action on ETU regulation. Thus, studies to demonstrate disruption in thyroid hormone economy; comparative sensitivity to inhibition of thyroperoxidase, for example, between rat, dog, monkey (by ETU), would be extremely valuable in extrapolations to humans.

Although the paradigm tested by NTP involving perinatal exposures failed to provide convincing evidence of increased sensitivity in either rats or mice, such paradigms warrant further evaluation as they may provide additional compound-related effects in developing infants. Therefore, the data generated should be carefully examined by the Agency.

The surface area *vs.* body weight normalization for scaling of effect and dose data from animal to man was addressed from both perspectives. The Panel considers the Agency's conversions based on surface area to body weight relationships as defensible, because they reflect differences in metabolic rates per unit weight in large versus small mammals and excretion rates of chemicals. Plasma concentrations of ETU and metabolites offer a solution to this problem as it aids assessment of chemical residence time and exposure of organs at risk. While half life data is useful for comparison of exposure, clearance is a more fundamental indicator of ETU exposure. Each species, including man, may have metabolic route and rate differences which affect both the site and extent of toxicity. Much more pharmacokinetic data are needed to facilitate interspecies comparisons.

The information provided to the Panel elicits concern for effects in addition to the carcinogenic effects observed. For example, an increase in TSH and decrease in thyroid hormone was seen as well as possible thyroid effects on neural and osseous structures. In humans, relative hypothyroidism occurring shortly after birth

during periods of rapid brain development has severe effects on brain growth and function in the young child. Other pituitary hormones (e.g., growth hormone) and hormones such as ACH (adrenocortical hormone) should be measured after administration of ETU as they may exert permissive action on the observed ETU toxicity or offer additional sites of toxicity. At a minimum they will aid investigation of mechanism of effect. For example, EBDC pesticides such as maneb and mancozeb contain zinc and/or manganese. Chronic manganese toxicity in humans but not rodents is characterized by Parkinson's-type symptoms due to irreversible destruction of those brain tissues that normally contain neuromelanin. Whether manganese is biologically available from the metabolism of such EBDCs is unknown.

For The Chairman:
Certified as an accurate report of Findings:

Robert B. Jaeger
Designated Federal Official
FIFRA Scientific Advisory Panel
Date: May 31, 1990

Agency Response: The Agency's response to the toxicological issues raised by the SAP comments has already been noted in Unit II of this Notice. In brief, the Agency has determined that ETU is a Class B_2 carcinogen based upon data showing the occurrence of adenomas and carcinomas in both mice and rats, the occurrence of tumors in the liver of the mouse and thyroid of the rat, and the increased incidence of carcinomas in the liver and thyroid of the mouse and rat, respectively, in a dose dependent manner.

A detailed description of the Agency's rationale for selecting the mouse for the purpose of calculating risk can be found in Unit II of this document.

The Agency's approach to calculating the Q_1^*, as proposed in the Health Effects Division Peer Review document dated September 26, 1991 (Ref. 9), was also reaffirmed as a result of the second SAP hearing held on September 18, 1991.

The Panel also expressed concern about groundwater contamination and potential ecological effects of EBDC compounds and ETU. Data have been required as a part of the Registration Standards which will address these concerns.

B. Public Comments to the SAP

The Rohm and Haas Company has submitted written responses to comments made by members of the Science Advisory Panel (SAP) during the May 15, 1990 SAP meeting on the EBDC's and ETU. The SAP suggested that the anti-thyroid effects of ETU and possible effects on neural and osseous structures might pose a potential hazard on early brain development in humans. Rohm and Haas believes that this concern is unfounded based on available data. Data show that the rat is the most sensitive species in terms of anti-thyroid effects and that the half-life of circulating thyroid hormones in rats is shorter than in humans. In Rohm and Haas' view, this provides a mechanistic base to support that humans are less sensitive to anti-thyroid effects.

Also, anti-thyroid effects and the possible secondary effects on neural and osseous structures occurred only when high doses of ETU were given to animals. Therefore, Rohm and Haas concludes that low dietary exposure to children resulting from ETU does not pose a hazard.

Response. The Agency is in general agreement with regard to Rohm and Haas' statements that (1) the (male) rat is the most sensitive species, (2) the half-life of circulating thyroid hormone in rats is shorter than in humans, and (3) that this provides a mechanistic base to support the argument that humans are less sensitive to anti-thyroid effects than rats.

In the PD 2/3, developmental risk from dietary exposure to ETU from consumption of food treated with EBDC pesticides was estimated by comparing the average exposure estimates of each EBDC chemical (mg/kg body wt./day) to the NOEL from a rat teratology study. The comparison between exposure and the NOEL is expressed as a Margin-of-Exposure (MOE). An acute dietary exposure analysis with anticipated ETU residues from each EBDC chemical was used to estimate the distribution of single-day exposure for certain population subgroups, which in this case are females of child bearing age. The analysis assumes that ETU levels occur uniformly within each food commodity at the anticipated residue levels. Margins-of-exposure for consumers of foods treated with EBDCs and presumed to contain ETU residues ranged from 770 for maneb to 5,000 for mancozeb.

With regard to the neuro-behavioral effects tested for in the NTP rat study which included both *in utero* and *non-in utero* exposure, data reveal that the Margin-of-Safey (MOS) ranges from 330 for non-nursing infants to 7,894 for the general population for the lowest dose tested of 0.45 mg/kg/day. Analysis of the data indicated no apparent neurobehavioral effects for the parameters tested at any dose level at the end of 9 months or 2 years. The Agency has based its reference dose (RfD) on a 2-year chronic feeding rat study conducted by Graham (1975). The RfD is based on the lowest dose tested which was the lowest effect level. The effect observed at the lowest dose tested of 5.0 ppm (0.25 mg/kg/day) was thyroid hyperplasia. The range of doses in the NTP chronic study was from 9 to 90 ppm (0.45 to 4.5 mg/kg/day) for perinatal administration and from 25 to 250 ppm (1.24 to 12.5 mg/kg/day) for adult exposure. The thyroid gland was clearly affected at all doses tested without an adverse effect on neurobehavior.

The registrant appears to imply that high doses of ETU result in anti-thyroid effects with secondary effects upon neural and osseous structures. It should be pointed out that the available data for rats and mice indicate that secondary effects on neural and osseous structures do not necessarily result from inhibition of the thyroid gland since thyroid inhibition in mice does not result in developmental effects. Additionally, in the rat, doses as low as 5.0 ppm have been shown to result in thyroid inhibition in the most sensitive species, thereby challenging the phrase that anti-thyroid effects occurred only when high doses of ETU were given to animals.

The SAP raised a concern about potential adverse neurotoxic effects due to manganese derived from EBDC residues. Rohm and Haas claims that no potential adverse health effects exist from manganese added to the human diet as a result of the use of EBDC fungicides.

The Agency has estimated manganese dietary exposure from maneb and mancozeb as a percent of the daily diet. The daily diet generally contains 2 to 5 mg of manganese, which is an amount sufficient to meet human requirements. In order to maintain a positive manganese balance, daily dietary intakes of 0.2 to 0.3 mg manganese per kilogram body weight have been recommended for children. The combined total manganese exposure from both mancozeb and maneb to the daily dietary intake for manganese was estimated for adults (0.00221 mg/kg/day), children 1 to 6 years of age (0.0062 mg/kg/day), and non-nursing infants (0.0050 mg/kg/day). These values represent 0.89, 0.50, and 0.60 percent of the recommended daily intake, respectively. The exposure estimates were based on the same exposure data for mancozeb and maneb that were used in estimating the dietary risk for carcinogenicity from ETU for these two fungicides in the PD 2/3. Therefore, the Agency agrees with the registrant that no potential adverse health effect exists from manganese added to the human diet as a result of the use of EBDC fungicides mancozeb and maneb.

C. Comments of the Scientific Advisory Panel -September 18, 1991

Due to deliberation within the HED Peer Review Committee, the Agency requested comments from the Panel relative to the inclusion of the 33/100 ppm (low) dose group for risk characterization. EPA presented this issue on the EBDCs at a public meeting of the Scientific Advisory Panel held in Arlington, Virginia on September 18, 1991. The Panel issued its response in a written report of October 2, 1991. The Panel's report is reproduced below in its entirety:

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel --A Set of Scientific Issues Being Considered by the Agency in Connection with a Dose-Response Analysis for Ethylene Thiourea (ETU).

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of a set of scientific issues regarding the Environmental Protection Agency Peer Review Committee's review of a dose-response risk assessment for the carcinogenic effects of Ethylene Thiourea (ETU) in rats and mice. The review was conducted in an open meeting held in Arlington, Virginia, on September 18, 1991. Panel members present for the review were Dr. Edward Bresnick (Chairman), Dr. Mont Juchau and Dr. Peter Magee (Dr. Curtis Travis was recused for the proceedings). In addition, Dr. Edmund Crouch of Cambridge Environmental, Inc., Dr. Richard Griesemer and Dr. Christopher Portier of the National Institute of Environmental Health Sciences, served as Agency representatives; and Dr. Dale Hattis of Clark University, and Dr. Ernest McConnell of Raleigh, NC served as Special Government Employees on the Panel.

Public notice of the meeting was published in two **Federal Registers** on Friday, August 23, 1991 (56 FR 41843) and Friday, September 13, 1991 (56 FR 46616).

Oral presentations were made by the EBDC/ETU Task Force: Mr. Edward Ruckert, Dr. Gary Flamm, Dr. Thomas Starr, Dr. Robert Sielken, Jr., and Dr. Kenny Crump.

Written comments were received from the EBDC/ETU Task Force members: Atochem North America, Inc., BASF Corporation, E.I. du Pont de Nemours and Company, and Rohm and Haas Company.

Note: Prior to the Panel's discussion and deliberations on ETU, an announcement was made that the ETU Task Force had expressed concern over a possible conflict of interest regarding Dr. Travis. Although discussion between the Designated Federal Official (DFO, FIFRA SAP) and the EPA Office of General Counsel (OGC Ethics Office), prior to the afternoon discussion of ETU, failed to substantiate the alleged conflict of interest, Dr. Travis informed both the DFO and the Chairman of the FIFRA SAP that he recused himself from all proceedings on ETU before the Panel, both public and private discussions of the issues. This does not reflect any real conflict of interest regarding the matter before the Panel, but rather the belief by Dr. Travis that (1) there were several other experts on the Panel who were equally capable of discussing the issues on ETU, (2) at such late notice, it gave the "appearance" of a problem, (3) when there is no benefit to be gained there should be no risks taken, and (4) the matter deserved more detailed written response by OGC to verify there is no conflict of interest, and to prevent unnecessarily impugning the reputation and scientific integrity of the FIFRA SAP.

In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency, the Panel unanimously submits the following report.

Report of Panel Recommendations

The Agency requested comments from the Panel relative to the Peer Review Committee's recommendations for appropriate use of the 33/100 ppm dose group for risk characterization considering that:

- this group represents several design flaws,
- necessitates the exclusion of the highest dose group (1000 ppm) because of the lack of (linearized multistage) model fit,
- but provides some valid and significant biological data at a lower exposure level and thus may be more relevant for low dose extrapolation than data points with high exposure and nearly saturated tumor response. Specifically, the Panel was asked to provide, to the extent possible, the scientific arguments for either inclusion or exclusion of the low dose data point in the dose response assessment.

Panel response. The Panel is of the opinion that adequate data should always be included unless there is strong reason to exclude them. In this case, there is a strong reason for the Agency's standard approach which results in the exclusion of the highest dose group since its inclusion was associated with gross distortion of estimates of the probable effects at lower doses when used in the Agency's standard dose-response formula (e.g., linearized multistage model).

The Panel felt strongly that the data from the 33/100 ppm group should be included in the analyses. The arguments for inclusion are:

1. The usual form of the linearized multistage model is probably not statistically appropriate for use in calculating the Q_1^* if all data except the control show over 90 percent rates of cancer.

2. Whole life exposure (the diagonal in the factorial experimental design) is probably most appropriate for utilization for public health purposes.

The principal argument against using the low dose point is potential litter bias, and this appears to have been relatively well addressed in the analyses presented to the Panel.

The Panel noted that the available data would not likely enable the robust detection of an interactive effect between the effects of pre-weaning and post-weaning exposure for the liver cancer endpoint if such an effect were to have been present. Despite the fact that not enough information exists to statistically evaluate the potential for a protective effect of the prenatal exposure, such an effect is not seen in the high dose groups. There is also supporting evidence for this view since no consistent patterns of interaction were observed in other tissues.

The Panel was informed during the meeting that some pharmacokinetic data exist for ETU. The Panel suggested that the analysis could be improved by using (and if necessary gathering) pharmacokinetic data which would allow expression of the results in terms of the internal dose of ETU [e.g., area under a curve (AUC) of concentration *vs.* time following comparable oral exposures, if possible based on experiments in subchronically dosed animals]. Pharmacodynamic data (e.g., the dynamics of thyroid hormone changes and cell proliferation responses in the thyroid and liver) may also aid in producing an improved estimation of low dose risks.

For The Chairman:

Certified as an accurate report of Findings:

Robert B. Jaeger
Designated Federal Official
FIFRA Scientific Advisory Panel
Date: October 2, 1991

Agency Response. After further analysis and consideration of the data sets, the Agency still believes that the 0.11 Q_1^* estimate should be used in the risk assessment because:

(1) The method of estimating the 0.11 Q_1^* is consistent with the recommendation of HED's Peer Review Committee as well as Agency policy.

(2) Even though the full data set of the diagonal yields a slightly greater Q_1^* than the pooled data set, the increased dose does not appear to be biologically or numerically meaningful. To illustrate this point, a sensitivity analysis of the doses in the diagonal data set was performed. It was found that, among other things, theoretically decreasing the number of animals manifesting tumors by only one animal in the high dose group resulted in an unacceptable fit of the data to the linearized multistage model. This would then lead to the high dose (i.e., 1000 ppm) being dropped from the estimations resulting in a statistically acceptable fit of the remaining doses to the model and a Q_1^* of 0.11.

D. Comments of the Secretary of Agriculture

The comments of the U.S. Department of Agriculture in response to the Notice of Preliminary Determination, Draft Notice of Intent to Cancel and the Technical Support Document, dated March 20, 1990, are printed in full below:

Mr. Douglas D. Campt
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, SW,
Washington, DC 20460

Dear Mr. Campt:

This is the Department of Agriculture's

preliminary response to the draft notice of intent to cancel pesticide products containing the ethylene bisdithiocarbamates (EBDCs). The integrated management approach that has always been used in disease control efforts requires the availability of a variety of pest control chemicals. With this in mind, the USDA is coordinating an assessment of the use of fungicides in agricultural production. We will be furnishing you two separate reports on the major fungicides in the near future. You should receive our draft biological assessment within the next several weeks. EPA staff have been present at all the meetings of the team and have had full access to preliminary data. You will also receive, within the next 3 months, a report entitled "Implications of the Use of Fungicides in Agriculture." This is an overview report and will discuss among other things potential for fungal induced hazards and the potential impact on the diet from an inadequate food supply.

In our opinion, there is no compelling evidence of chronic toxicity in humans resulting from use of EBDC fungicides. The available residue data indicate a high percent of samples contain no EBDC or ETU residues. There are no substantiated data indicating EBDC residues present environmental problems. We are particularly concerned about the loss of many minor uses, some of which the registrants have voluntarily withdrawn. If necessary, various measures can be taken, such as lowering tolerances or increasing the pre-harvest interval. In view of these considerations, the Department urges the Agency to reevaluate the benefits that result from the many uses of these valuable fungicides.

The Department applauds the EPA decision to wait for the market basket survey results before making a final decision, which we understand will not be made until 1991. Available information on residues from the Food and Drug Administration as well as State agencies gives every indication that residue levels are much lower than those estimated by the Agency. Since a great deal of data currently exist on these fungicides, we strongly recommend that the Agency utilize the scientifically valid figures rather than base a position on estimated values that appear substantially greater than those actually measured. In view of the importance of the EBDCs in agricultural production, a reassessment of residue levels seems appropriate. The USDA would be pleased to cooperate with EPA in arranging a panel of experts from State, Federal, and academic institutions that would determine in the most scientific manner possible what residue levels are appropriate in this risk assessment.

We are concerned that the resistance factor was neither adequately addressed nor was sufficient consideration given to the ramifications of the loss of the EBDCs. A copy of our report on "Fungicide Resistance in the United States" was furnished to the Agency through Dr. E. N. Pelletier in June 1989. Another copy is attached for your use. A variety of fungicides with different modes of action are essential for the control of plant diseases. The multisite mode of action makes EBDCs extremely valuable in pest management programs. The development of new fungicides has moved towards compounds that are more specific in their modes of action. A consequence of high specificity has been the development of fungal resistance to these compounds; and thus, the older protectant fungicides (such as the EBDCs) must be used as companions to reduce the chance of fungal resistance problems. Without the use of EBDCs, overall resistance losses might initially be less than 50 percent; however, losses by individual producers could approach 100 percent. In addition, failure to control new races of pathogens will accelerate disease control problems in subsequent growing seasons and impact more producers.

The EBDC fungicides play a major role in the production of fruits and vegetables. A recent report by the National Academy of Sciences recommended that Americans include several servings of fruits and vegetables in their daily diet. A number of government agencies have made similar recommendations. Loss of the EBDCs would have a significant impact on the availability of this produce. Varieties, their cost and longevity (storage and shipping), would be severely impacted. In addition, failure to control fungal diseases can lead to food contaminated with hazardous fungal products and plant defense chemicals.

In determining the impacts of cancelling the EBDCs, the Agency fails to consider regional impacts. In humid areas of the country, disease pressures on production are generally greater and more control measures are required. The Department feels that agriculture should be maintained throughout the United States and not confined, due to regulatory restrictions on pest control materials, to segments of the country. In addition, the increased costs of alternatives to the EBDCs will have many ramifications ranging from reductions in the farmers' profits to increased costs to the consumers.

The number of crops that will be affected by the proposed regulatory action is lengthy. We would like to make several points in relation to some of these.

- Downey mildew is often a serious disease in California lettuce production. Maneb, or maneb in combination with metalaxyl (to avoid buildup of resistance to metalaxyl), has been used to effectively control the disease.
- In the absence of host plant resistance to disease, maneb is critical in spinach production. The only other registered materials are phytotoxic.
- EBDCs are primary fungicides in the production of tomatoes in California and Florida. In addition to controlling fungal diseases, an EBDC fungicide in combination with a copper fungicide is the only available control of bacterial diseases on tomatoes as well as peppers in Florida.
- EBDCs are important in control of both early and late blights in potatoes. Consideration must be given to the low profit margins in potato production since alternatives, if available, would probably negate profits.
- A number of key crops which should be included in the market basket survey to determine more accurately dietary exposure are not. These are spinach, leaf lettuce, carrots, succulent beans, and peaches. Not only do these crops represent important registration needs, but data from these crops would be extrapolated to other crops including snapbeans, lima beans, turnips, celery, endive, fennel, rhubarb, collards, kale, and mustard greens to support continued registration.
- Mancozeb and metiram have been applied extensively in apple disease management programs at 40 to 50 percent below label rates in many mid-Atlantic orchards. Their use in combination with newer, specific fungicides is extremely effective in preventing the development of disease resistance.
- EBDCs have played an important role in the production of marketable mushrooms. The loss of zineb leaves mushrooms without a registered EBDC fungicide and lowers the possibility of meeting the blemish-free quality of standard.

We hope these comments are useful to you in your deliberations, and hope that you will make every effort to be sensitive to the needs of agriculture and the American consumer.

Sincerely,
Charles L. Smith
Coordinator, Pesticides and Pesticide Assessment

Response. EPA has considered the benefits information provided by the USDA. This information is referred to throughout Unit V of this Notice which summarizes EPA's benefits assessment and evaluation of comments and additional data received in response to the PD 2/3.

E. SAP and USDA waiver of further review

Recently, for the reasons discussed below, the Agency requested that the SAP and USDA waive further review of this Notice of Intent to Cancel. When the Agency proposed its action in December, 1989, the SAP and USDA were each sent a Draft Notice of Intent to Cancel 45 of 55 food uses of the EBDC fungicides as well as other uses.

In its Final Determination, the Agency is requiring that certain modifications be made to registrations of the 10 crop uses which the Agency originally proposed to retain. These changes are consistent with those requested by the ETU Task Force or data currently available to support the particular use. The changes include setting the maximum number of applications per season, modifying preharvest intervals, modifying application intervals, and/or reducing application rates. The Agency believes that these changes will not affect the efficacy of EBDC fungicides on these uses.

The SAP has waived any further review. USDA recommended minor changes which the Agency adopted for

this Final Determination. The following is the full text of the USDA response:

Mr. Douglas D. Campt
Director
Office of Pesticide Programs (H7501C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Dear Mr. Campt:

This is in response to your request that the U.S. Department of Agriculture (USDA) waive further review beyond the minor modifications made to registrations proposed to be retained in the draft Notice of Intent to Cancel (NOIC) 45 of the 55 food uses of the EBDC fungicides that the Department received in December 1989. We have reviewed the modifications and believe these changes that include setting maximum number of applications per season, modifying preharvest intervals, modifying application intervals, and/or reducing application rates will not impact the use of these chemicals in current disease management practices. The Department is pleased that the Agency has taken into consideration the regional differences in disease pressure when modifying the registrations.

Thus, in view of our agreement with modifications to the specified registrations and our response to the December 1989 NOIC, USDA waives further review of the NOIC. We would like to reiterate the statements made in our previous response (March 20, 1990) that there is no compelling evidence of chronic toxicity in humans resulting from use of EBDC fungicides, that EBDCs are extremely valuable in pest management programs designed to avoid resistance problems, and that EBDCs play a major role in the production of fruits and vegetables.

In your final determination, we hope you will make every effort to be sensitive to the needs of agriculture and the American consumer.

Sincerely,
Nancy N. Ragsdale
Director
National Agricultural Pesticide Impact Assessment Program

VII. Risk/Benefit Assessment and Initiation of Final Determination Actions

A. Conclusions of the Risk/Benefit Assessment

Based on the information summarized and presented in this Notice, EPA has determined that the uses of the EBDCs as currently registered pose unreasonable dietary and worker risks.

1. *Dietary risks.* EPA has determined that the estimated dietary risks to the overall U.S. population from consumption of EBDC-treated crops exceed the estimated benefits of continued registration. Accordingly, EPA is announcing its intent to cancel all mancozeb, maneb, and metiram products registered for 1 or more of the following 11 uses: apricots, carrots, celery, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, and turnips. Additionally, EPA is announcing its intent to cancel all remaining mancozeb, maneb, and metiram registrations unless the changes to registration to reduce dietary risks required herein are made.

In the Preliminary Determination, the Agency proposed to cancel 45 of the 55 food uses of mancozeb, maneb, and metiram. This action was proposed because the estimated total upper-bound carcinogenic risk resulting from dietary exposure to EBDCs for all 55 food uses (3×10^{-4}) was not outweighed by the benefits ($46 to $75 million in first-year losses to growers (i.e., producer impacts) and $90 to $305 million in losses to society (i.e., efficiency impacts)). The proposed cancellation would have allowed uses with an estimated dietary risk of 3×10^{-6} to continue.

Today, EPA is announcing its intent to cancel EBDC products with 1 or more of the 11 uses listed above. With respect to EBDC products bearing 1 or more of the 45 sites for which the Agency is requiring modifications to lower risk, the Agency is announcing its intent to cancel those products if the required changes are not made. [1] The current estimate of lifetime dietary risk to the overall U.S. population from all 56 sites is 1.8×10^{-5}. The 56 uses represent an estimated $290 to $630 million in benefits. The 11 cancellations and modified registrations involved in this action will reduce estimated lifetime dietary risk to 1.6×10^{-6}. These risks are outweighed by the benefits associated with the 45 remaining uses after considering the required modifications. The estimated individual dietary risks for each of the 56 commodities are discussed in Unit III of this Notice and are listed in Table 1 in Unit III.B. The estimated benefits of EBDCs on individual food commodities are detailed in Unit V of this Notice and are summarized in Table 1 in Unit III.B. of this Notice.

The estimated dietary risks resulting from consumption of EBDC and ETU residues on individual commodities treated with EBDC fungicides ranges from 10^{-10} to 10^{-6}. Although many of the estimated individual risks posed by certain food uses are minimal, EPA believes that the estimated cumulative risk of 10^{-5} from all 56 food uses is unacceptable, even in light of estimated benefits that, in total, range from $290 to $630 million.

In developing the Final Determination, EPA considered the estimated benefits resulting from the EBDC use on each individual commodity and compared those estimated benefits to the estimated risk posed from dietary exposure to the EBDC and ETU residues on that commodity. The availability and toxicity of alternative fungicides was also considered, along with potential risk reduction measures for continued use of the EBDCs. Cost-effectiveness, where applicable, was used as a tool to assist in quantitatively comparing the estimated dietary risks to the estimated benefits.

Alternative fungicides. For each of the 56 food uses, EPA estimated the relative risk (compared to the estimated risk of the EBDCs) and the efficacy of the alternative fungicides. For a number of sites being cancelled (e.g., collards, mustard greens, and spinach), there is no viable alternative fungicide. For sites being cancelled where there are alternative fungicides (i.e., apricots, carrots, celery, nectarines, peaches, rhubarb, and succulent beans), the Agency believes that chlorothalonil is the most likely alternative to EBDCs for control of fungal disease. EPA estimates that switching from EBDCs to chlorothalonil for these sites will reduce risk.

One of the weaknesses in EPA's analysis in comparing the estimated risk of the EBDCs to its alternatives is the differences among the data bases. The two alternatives most likely to be used if the EBDCs were not available are captan (an alternative for apples and grapes) and chlorothalonil. To estimate dietary exposures from captan and chlorothalonil, the Agency relied primarily on Food and Drug Administration (FDA) monitoring data. Dietary exposure estimates for the EBDCs were based on market basket data and field trial data. Exposure estimates based on monitoring data would be expected to be lower than those based on field trial data but higher than those based on market basket data.

Despite this weakness, EPA believes that the conclusions reached in its analysis of the alternatives to the EBDCs and the incremental risks resulting from various shifts in use are valid. Further, EPA believes that cancellation of the EBDCs for apricots, carrots, celery, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, and turnips will not

[1] Because all 55 uses remain on 1 or more registered end-use products (in spite of the technical registrants' September 6, 1989 action to voluntarily delete 42 of the 55 uses from their registrations), EPA has considered all 55 food uses in this Final Determination. Also, it now appears that there are 56 uses of EBDCs (i.e., 11 uses being cancelled and 45 being retained). In the EBDC PD 2/3, dry and succulent beans were listed as 1 site and in the PD 4 they are listed as 2 sites.

result in higher dietary risk due to the shift in fungicide usage to chlorothalonil.

Risk reduction measures. Recognizing the overall importance of the EBDCs as an agricultural fungicide in both the economic benefits it appears to provide and the importance of its role in delaying or preventing resistance of fungal organisms to other pesticides, EPA examined ways of reducing risks to the point where the estimated cumulative benefits of EBDCs outweighed its estimated cumulative risks. Generally, potential risk reduction measures include increasing the preharvest interval, decreasing the number of applications, and/or decreasing the application rate. In the PD 2/3, EPA urged commenters to consider such risk reduction measures and to suggest and support potential modifications in use patterns, along with residue data demonstrating the resulting residue levels of EBDCs and ETU and the efficacy of the altered use pattern. The Agency received such information for only a few sites. The International Apple Institute (IAI) provided field trial data for an alternative use pattern on apples that would require a longer preharvest interval and lower application rate than the currently registered use pattern to significantly reduce the estimated dietary risk for EBDCs and ETU on apples. The Hawaiian Papaya Industry Association growers also submitted data on an altered use pattern. Leafy green growers and food processors submitted preprints of studies to be published on residue and efficacy data for an altered use pattern. Other commenters provided their opinion on risk reduction measures, such as extending the preharvest interval and reducing application rates, for other sites. However, data were generally not submitted to support these measures.

Cost-effectiveness. Cost-Effectiveness (C-E) is a tool used to compare the estimated loss of benefits to society which are associated with the loss of an EBDC use (cost) on a particular site to the estimated reduction in carcinogenic dietary risk of that site (effectiveness). The C-E coefficient is an estimate of the societal cost per cancer case avoided.

EPA estimated C-E coefficients for those sites where estimated benefits were quantified; these estimates are listed in Table 1 in Unit III.B. of this Notice. As discussed in Unit V, the PD 4 estimated benefits include both producer and consumer impacts. The C-E coefficients were then used as a guide to rank the relative importance of the 56 sites. C-E was only used as a guide, and one tool of many, in developing the Final Determination as the Agency recognized the limitations of C-E in the EBDC analysis. First, all 56 sites were not included in the ranking because cost-effectiveness was unavailable for certain sites. Second, where C-E was available, the coefficients for many of the estimates did not incorporate estimated consumer impacts because they were not quantifiable due to a lack of information.

Nonetheless, EPA considered C-E coefficients to be a valuable tool in determining the relative importance of the 56 sites. Even though estimated consumer impacts were not always incorporated (as in the case of potatoes), most of the sites being retained had very high C-E coefficients. A high C-E coefficient indicates that it would be expensive to reduce dietary risk associated with the use of EBDCs on a particular site relative to risk reduction for other sites. A low C-E coefficient indicates that it would be a relatively inexpensive to reduce dietary risks associated with the use of EBDC on a particular site.

For the 11 sites being cancelled (i.e., those for which modifications cannot be made), even if estimated consumer impacts had been fully quantified and the C-E estimate were higher, EPA would have still arrived at the same Final Determination. Generally, the 11 sites being cancelled pose high estimated dietary risks, especially for the infant and children population subgroups.

a. *Protectiveness to infants and children.* Infants and children may be more highly exposed to EBDC and ETU residues than the overall U.S. population due to the high consumption of foods such as apples and bananas relative to body weight. EPA believes that today's Final Determination is protective of infants and children. For thyroid effects, the Agency has estimated the percent of reference dose utilized (i.e., percent RfD) for the infants and children subgroups. For the sites proposed to be retained with modifications, the sum of the individual percent RfD estimates is less than 100 percent for each of the infants and children subgroups. For carcinogenic risk, EPA has estimated the 1–year dietary risk for the infants and the children subgroups. For the sites proposed to be retained with modifications, the sum of the individual 1–year carcinogenic risk estimates is 6.4×10^{-6} for the infants subgroup and 4.6×10^{-6} for the children subgroup (Ref. 33). Assuming that a given individual would be exposed to EBDCs and ETU at the infant and child level of exposure for their entire life, the estimated cumulative risk for the sites being retained would be 4×10^{-6} and 3×10^{-6}, respectively. These risk estimates are in the same order of magnitude as the risk for the overall U.S. population (i.e., 1.6×10^{-6}). The Agency believes that this apparent higher risk to infants and children is not a significant increase. Additionally, the Agency believes that the estimated cumulative dietary risks to infants (4×10^{-6}) would be an overstatement of potential lifetime risk because people are not exposed to EBDC and ETU residues at the infant and child level for a lifetime.

The Agency has commissioned the National Academy of Sciences (NAS) to examine current Agency practices and policies to ascertain that children are adequately protected from pesticide residues in their diet. NAS is gathering data on actual pesticide residues in food and is using a computer model to analyze children's exposure to these compounds in their diet. Also, the Academy is examining current methods used by EPA for setting safety factors and determining acceptable levels of exposure to carcinogens for infants and children. NAS is expected to complete its report in the spring of 1992.

b. *Stability of the dietary risk estimates.* In developing this Final Determination, the Agency was concerned that the estimated lifetime dietary risk not increase over time.

To assure that this estimated cumulative dietary risk will not increase significantly, EPA is requiring that use patterns be amended to specify all variables in the use pattern (i.e., the application rate, maximum number of applications, application interval, and preharvest interval). In the past, the number of applications, application intervals, and preharvest intervals were not specified for all EBDC use sites.

Further, EPA believes that, where appropriate, use patterns no higher than those used during the year that the market basket survey was conducted should be required on product labels; most of the PD 4 dietary residue estimates were based, in part, on market basket data.

For the market basket survey, "typical" use patterns were assumed. "Typical" use patterns were delineated by examining past use patterns and by considering information provided by commenters. Requiring that labels be amended to reflect such use patterns will generally allow the use of the amount of pesticide actually needed by growers to efficaciously control disease. However, the Agency recognizes that certain growers may need higher rates. There are mechanisms to enable the

Agency to consider requests for such needs. Among other things, appropriate residue data would need to be provided before the Agency could make a risk/benefit determination prior to action on the request.

Finally, reinstatement of certain EBDC uses should result in increases in the percent of crop treated; however, the Agency does not believe these increases will exceed the estimates used for the Final Determination. EPA considers the historic usage of the EBDC fungicides to be well-established. Only a significant event such as cancellation of a major alternative would likely increase the market share of EBDCs in the overall fungicide market.

The required use patterns for each of the food uses being retained are detailed in Unit VII.B.

c. *Sites eligible for amended labels as a result of the Special Review.* In September 1989, the EBDC technical registrants amended their labels to delete 42 of the 55 registered food uses of mancozeb, maneb, and metiram. Those sites which were registered on any mancozeb, maneb, or metiram label at the time of the Task Force's 1989 action and which are not being cancelled by today's action, and which meet the requirements of this Notice, are eligible for continued registration under this Notice. The sites which are now eligible for continued registration on amended mancozeb, maneb, and metiram labels as a result of the outcome of this Special Review are listed in the following Table 4. Elsewhere in this Notice are requirements applicable to the 45 uses that may remain pursuant to this Notice, if required modifications are made.

TABLE 4.—SUMMARY OF THE SITES ELIGIBLE FOR RESTORATION ON AMENDED LABELS AS A RESULT OF THE SPECIAL REVIEW.

Food Crop	Eligible for Restoration?		
	Maneb	Mancozeb	Metiram
Almonds	YES	NO	NO
Apples	YES	YES	YES
Asparagus	NO[2]	YES	NO
Banana	YES	YES	NO
Barley	NO	YES	NO
Broccoli	YES	NO	NO
Brussels Sprouts	YES	NO	NO
Cabbage:			
Cabbage	YES	NO	NO
Chinese Cabbage	YES	NO	NO
Cantaloupe	YES	YES	NO
Casaba Melons	YES	YES	NO
Cauliflower	YES	NO	NO
Corn:			
Sweet and Pop	YES	YES	NO
Field	NO	YES	NO

TABLE 4.—SUMMARY OF THE SITES ELIGIBLE FOR RESTORATION ON AMENDED LABELS AS A RESULT OF THE SPECIAL REVIEW.—Continued

Food Crop	Eligible for Restoration?		
	Maneb	Mancozeb	Metiram
Cotton	NO	YES	NO
Crabapple/Quince	NO	YES	NO
Cranberries	YES	YES	NO
Crenshaw Melons	YES	YES	NO
Cucumbers	YES	YES	NO
Dry Beans	YES	NO	NO
Eggplant	YES	NO	NO
Endive	YES	NO	NO
Fennel	NO	YES	NO
Figs:			
Caprifigs[1]	NO	YES	NO
Kadota	YES	NO	NO
Grapes	YES	YES	NO
Honeydew	YES	YES	NO
Kale	YES	NO	NO
Kohlrabi	YES	NO	NO
Lettuce:			
Head	YES	NO	NO
Leaf	YES	NO	NO
Oats	NO	YES	NO
Onion:			
Dry bulb	YES	YES	NO
Green	YES	NO	NO
Papaya	YES	YES	NO
Peanuts	NO[3]	YES	NO
Pears	NO	YES	NO
Pecans	NO	NO	NO
Peppers	YES	NO	NO
Pineapples[2]	NO	YES	NO
Potatoes	YES	YES	YES
Pumpkins	YES	NO[3]	NO
Rye	NO	YES	NO
Sugar Beets	YES	YES	NO
Squash:			
Summer	YES	YES	NO
Winter	YES	NO	NO
Tomatoes	YES	YES	NO
Watermelon	YES	YES	NO
Wheat	NO	YES	NO

[1]Caprifigs is a non-food use.
[2]The use of EBDCs on pineapple is for Seedpiece treatment only.
[3]There are no tolerances for these products. The affected registrants have agreed to delete these uses from product labels.

Just prior to the completion of this Final Determination, the Agency became aware of a few end-use registrants with EBDC products that have some uses for which there are no tolerances. The Agency has contacted these registrants to request that they delete the uses with no tolerances. The affected registrants have agreed to make the appropriate deletions when they submit label amendments to meet the requirements described elsewhere in this document. Should these deletions not occur, the Agency will undertake appropriate regulatory actions.

The Agency through this Notice proposes to cancel products bearing 1 or more of 11 uses for which modifications cannot be made. Further, the Agency proposes to cancel products bearing other specified uses unless required modifications are made. To register other uses not eligible for continued registration under today's Notice, interested registrants must seek new registration and meet registration requirements including certain data requirements. For further information, contact Susan Lewis, Product Manager Number 21, Registration Division (H7505C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *Industrial worker, agricultural worker, and homegardener risks.* Industrial uses of EBDCs include those for water cooling systems and oil drilling. Agricultural uses are those other than industrial or homegarden, which include but are not limited to: farming, commercial greenhouse applications, and commercial turf applications. Homegarden uses of EBDCs include those in and around the home such as garden, lawn, or tree/shrub applications.

a. *Industrial uses.* In the PD 2/3, the Agency proposed cancellation of nabam use in paper mills and sugar mills based on inadequate (i.e., below 100) margins of exposure (MOEs) for thyroid effects due to occupational exposure. Also, EPA proposed a label language requirement that all industrial workers applying EBDC pesticides wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, shoes, socks, and goggles or a face shield. Additionally, during mixing and loading, a chemical-resistant apron was to be worn.

EPA has reevaluated industrial occupational exposure to nabam (see Unit IV.B.), in light of new exposure data, and now estimates that all MOEs for thyroid effects are greater than 100; carcinogenic risks and developmental effects are not of concern. Thus, no industrial uses will be cancelled, unless required label modifications are not made. The Agency is requiring that labels be amended to require the use of protective clothing. See Unit VII.B. for a detailed description of the required label amendments.

b. *Agricultural uses.* In the PD 2/3, among other things, EPA proposed to cancel maneb use on grapes and commercial ornamentals because the estimated occupational risks from exposure while handling EBDC pesticides exceeded the benefits. Also, the Agency proposed a label language requirement that agricultural workers applying EBDCs wear the protective clothing described in paragraph VII.B. and that a 24–hour interim reentry interval be established.

EPA has reevaluated agricultural occupational exposure and risk to

EBDCs (see Unit IV.B.) and has concluded that the benefits exceed the risks, assuming certain modifications are made to registrations and labels. The Agency is requiring that labels be amended to require the use of protective clothing and to establish an interim reentry interval of 24 hours. See Unit VII.B. for a detailed discussion of the required label amendments.

c. *Homegarden uses.* In the PD 2/3, the Agency proposed to cancel the homegarden use of mancozeb on fruit trees and turf and homegarden use of maneb on vegetables, ornamentals, fruit trees, and turf because the long-term estimated risks exceeded the estimated benefits. Also, EPA proposed label language requirements that homeowners applying EBDC pesticides wear a long-sleeved shirt and long pants and rubber gloves; that gloves must be washed thoroughly with soap and water before removing; that clothes must be changed immediately after using the EBDC product and laundered separately from other laundry items before reuse; and that homeowners must shower immediately after use.

The Agency has reevaluated the risks to homegardeners from applying EBDCs and now estimates that for all uses except mancozeb on fruit trees and turf, the benefits exceed the risks, assuming that the required modifications are made. EPA has determined that the risks associated with the homegarden uses of mancozeb on fruit trees and turf exceed the benefits. Thus, the homegarden use of mancozeb on fruit trees and turf is proposed to be cancelled. No other homegarden uses will be cancelled unless the required modifications are not made. EPA is requiring that product labels bear certain clothing and hygiene language. See Unit VII.B. for a detailed discussion of the required label amendments.

B. Modifications to Terms and Conditions of Registrations

Based on the information summarized in Unit VII.A. of this Notice and discussed elsewhere in this Notice, the Agency has determined that the use of the EBDCs as currently registered poses unreasonable adverse effects to human health or the environment, and that certain modifications to the terms and conditions of registration are required to bring these products into compliance with the statutory standard for registration. Therefore, to avoid cancellation, registrations of subject EBDC products must be modified within the timeframe described in Unit VIII (Procedural Matters) to include the terms and conditions specified below. For each use site, other than those for which modifications are not possible to lower risk, EPA has specified the maximum application rate, the maximum number of applications per season, the application interval, and the minimum preharvest interval which will be allowed on product labels. For all sites except barley, oats, rye, and wheat, EPA may allow registrants to substitute a maximum seasonal use (i.e., lb. a.i./acre per season) for the maximum number of applications per season. The maximum seasonal use can be no greater than the maximum application rate multiplied by the maximum number of applications, which are specified below. Such a request for maximum seasonal use must be approved by the Agency and must be consistent with available residue data.

To avoid cancellation, all mancozeb, maneb, and metiram labels and product registrations bearing agricultural uses must be amended to include the following label statement: "If this product is used on a crop, no other product containing a different EBDC active ingredient may be used on the same crop during the same growing season."

1. *Almonds.* Maneb is registered for use on almonds. The Agency intends to cancel all maneb products registered for use on almonds unless the registrations and labelling are amended as follows: Maximum application rate– 6.4 lb. a.i./A; maximum number of applications per season–4; application interval–7 to 10 days; and minimum preharvest interval–5 weeks after petal fall.

2. *Apples.* Mancozeb, maneb, and metiram are registered for use on apples. The Agency intends to cancel all mancozeb, maneb, and metiram products registered for use on apples unless the registrations and labelling are amended as follows: All mancozeb, maneb, and metiram products registered for use on apples must state that the product may be used with either the pre-bloom use pattern or the extended application use pattern. Further, labels must state that the two treatment schedules (i.e., pre-bloom and extended) must not be combined or integrated. The pre-bloom use pattern must be at least as restrictive as the following: Maximum application rate–4.8 lb ai/A; maximum number of applications per season–4; application interval–7 to 10 days; and minimum preharvest interval–bloom. The extended application use pattern must be at least as restrictive as the following: Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–7; application interval–7 to 10 days; and minimum preharvest interval–77 days. These use patterns are consistent with the International Apple Institute data which were submitted in lieu of the required market basket survey data. Additionally, to avoid cancellation, all mancozeb, maneb, and metiram labels must include the following label statement: "It is recommended that this product be used in an Integrated Pest Management Program."

3. *Asparagus.* Mancozeb is registered for use on asparagus ferns after harvest of spears. The Agency intends to cancel all mancozeb products registered for use on asparagus unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–4; application interval–10 days; and minimum preharvest interval–180 days for all states except California and Arizona; minimum preharvest interval in California and Arizona–120 days. This use pattern is consistent with residue data submitted in support of asparagus.

4. *Bananas.* Mancozeb and maneb are registered for use on bananas. The Agency intends to cancel all mancozeb and maneb products registered for use on bananas unless the registrations and labelling are amended as follows: Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–10; application interval–14 to 21 days; and minimum preharvest interval–0 days. This use pattern is consistent with the typical use during the market basket survey period.

5. *Barley.* Mancozeb is registered for use on barley. The Agency intends to cancel all mancozeb products registered for use on barley unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–3; application interval–7 to 10 days; and minimum preharvest interval–26 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of sweet corn, which are translatable to barley.

6. *Broccoli.* Maneb is registered for use on broccoli. The Agency intends to cancel all maneb products registered for use on broccoli unless the registrations and labelling are amended as follows: Maximum application rate– 1.6 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–7 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of broccoli.

7. *Brussels sprouts.* Maneb is registered for use on brussels sprouts. The Agency intends to cancel all maneb

products registered for use on brussels sprouts unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–7 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of broccoli, which are translatable to brussels sprouts.

8. *Cabbage.* Maneb is registered for use on cabbage. The Agency intends to cancel all maneb products registered for use on cabbage (including chinese cabbage, tight-headed varieties only) unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–7 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of broccoli, which are translatable to cabbage.

The Agency intends to cancel all maneb products registered for use on all other varieties of cabbage (which would include loose-headed varieties of chinese cabbage) in California and Hawaii unless the registrations and labelling are amended as follows: Maximum application rate–1.2 lb. a.i./A; maximum number of applications per season–6; application interval–7 days; and minimum preharvest interval–7 days in California and 10 days in Hawaii. This use pattern is consistent with the two existing uses, which are in California and Hawaii.

9. *Cauliflower.* Maneb is registered for use on cauliflower. The Agency intends to cancel all maneb products registered for use on cauliflower unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–7 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of broccoli, which are translatable to cauliflower.

10. *Corn, field.* Mancozeb is registered for use on field corn. The Agency intends to cancel all mancozeb products registered for use on field corn unless the registrations and labelling are amended as follows: Maximum application rate–1.2 lb. a.i./A; maximum number of applications per season–10; and minimum preharvest interval–40 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of corn.

11. *Corn, sweet and pop.* Mancozeb and maneb are registered for use on sweet corn and popcorn. The Agency intends to cancel all maneb products registered for use on sweet corn and popcorn east of the Mississippi River and Arkansas and Louisiana unless the registrations and labelling are amended as follows: Maximum application rate–1.2 lb. a.i./A; maximum number of applications per season–15; application interval–3 to 10 days; and minimum preharvest interval–7 days. The Agency intends to cancel all maneb products registered for use on sweet corn and popcorn west of the Mississippi River (except Arkansas and Louisiana) unless the registrations and labelling are amended as follows: Maximum application rate–1.2 lb. a.i./A; maximum number of applications per season–5; application interval–3 to 10 days; and minimum preharvest interval–7 days. The Agency intends to cancel all mancozeb products registered for use on sweet and popcorn east of the Mississippi River and Arkansas and Louisiana unless the registrations and labelling are amended as follows: Maximum application rate–1.2 lb. a.i./A; maximum number of applications per season–15; application interval–4 to 7 days; and minimum preharvest interval–7 days. The Agency intends to cancel all mancozeb products registered for use on sweet and popcorn west of the Mississippi River (except Arkansas and Louisiana) unless the registrations and labelling are amended as follows: Maximum application rate–1.2 lb. a.i./A; maximum number of applications per season–5; application interval–4 to 7 days; and minimum preharvest interval–7 days. These use patterns are consistent with the typical use during the market basket survey period and/or residue data submitted in support of corn.

12. *Cotton.* Mancozeb is registered for use on cotton in the Southwestern United States. The Agency intends to cancel all mancozeb products registered for use on cotton unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–4; and minimum preharvest interval–mancozeb may not be applied after the bolls open. The label must specify a numerical minimum preharvest interval consistent with boll opening and the supporting residue data. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of dry beans, which are translatable to cotton.

13. *Crabapples/quince.* Mancozeb is registered for use on crabapples and quince. The Agency intends to cancel all mancozeb products registered for use on crabapples and/or quince unless the registrations and labelling are amended as follows: All mancozeb products registered for use on crabapples/quince must state that the product may be used with either the pre-bloom use pattern or the extended application use pattern. Further, the label must state that the 2 treatment schedules (i.e., pre-bloom and extended) must not be combined or integrated. The pre-bloom use pattern must be at least as restrictive as the following: Maximum application rate–4.8 lb. a.i./A; maximum number of applications per season–4; application interval–7 to 10 days; and minimum preharvest interval-bloom. The extended application use pattern must be at least as restrictive as the following: Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–7; application interval–7 to 10 days; and minimum preharvest interval–77 days. These use patterns are consistent with the International Apple Institute data which were submitted in lieu of the required market basket survey data and are translatable to crabapples/quince. Additionally, to avoid cancellation, all mancozeb products registered for use on crabapples/quince must include the following label statement: "It is recommended that this product be used in an Integrated Pest Management Program."

14. *Cranberries.* Mancozeb and maneb are registered for use on cranberries. The Agency intends to cancel all mancozeb and maneb products registered for use on cranberries unless the registrations and labelling are amended as follows: Maximum application rate-4.8 lb. a.i./A; maximum number of applications per season–3; application interval–7 to 10 days; and minimum preharvest interval–30 days. This use pattern is consistent with residue data submitted in support of cranberries.

15. *Cucumbers.* Mancozeb and maneb are registered for use on cucumbers. The Agency intends to cancel all maneb products registered for use on cucumbers unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–5 days. The Agency intends to cancel all mancozeb products registered for use on cucumbers unless the registrations and labelling are amended as follows:

Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–8; application interval–7 to 10 days; and minimum preharvest interval–5 days. These use patterns are consistent with the typical use during the market basket survey period and residue data submitted in support of cucumbers.

16. *Dry beans.* Maneb is registered for use on dry beans. The Agency intends to cancel all maneb products registered for use on dry beans unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–6; application interval–5 to 7 days; and minimum preharvest interval–30 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of dry beans.

17. *Eggplant.* Maneb is registered for use on eggplant. The Agency intends to cancel all maneb products registered for use on eggplant unless the registrations and labelling are amended as follows: Maximum application rate –1.6 lb. a.i./A; maximum number of applications per season–7; application interval–7 to 10 days; and minimum preharvest interval–5 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of tomatoes, which are translatable to eggplant.

18. *Endive.* Maneb is registered for use on endive. The Agency intends to cancel all maneb products registered for use on endive unless the registrations and labelling are amended as follows: Maximum application rate –1.6 lb. a.i./A; maximum number of applications per season–6, except in California which must be no more than 4; application interval–7 to 10 days; and minimum preharvest interval–10 days, except in California which must be at least 14 days. This use pattern is consistent with the typical use during the market basket survey period, residue data submitted in support of lettuce (which is translatable to endive), and information provided by commenters.

19. *Fennel.* Mancozeb is registered for use on fennel. The Agency intends to cancel all mancozeb products registered for use on fennel unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–8; application interval–7 to 10 days; and minimum preharvest interval–14 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of celery, which are translatable to fennel.

20. *Grapes.* Mancozeb and maneb are registered for use on grapes. The Agency intends to cancel all mancozeb products registered for grapes east of the Rocky Mountains unless the registrations and labelling are amended as follows: Maximum application rate–3.2 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–66 days. The Agency intends to cancel all mancozeb products registered for grapes west of the Rocky Mountains unless the registrations and labelling are amended as follows: Maximum application rate –2.0 lb. a.i./A; maximum number of applications per season–3; application interval–7 to 10 days; and minimum preharvest interval–66 days, except in California where no treatment may occur after bloom. The Agency intends to cancel all maneb products registered for use on grapes east of the Rocky Mountains unless the registrations and labelling are amended as follows: Maximum application rate–3.2 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–66 days. The Agency intends to cancel all maneb products registered for use on grapes west of the Rocky Mountains unless the registrations and labelling are amended as follows: Maximum application rate–2.0 lb. a.i./A; maximum number of applications per season–3; application interval–7 to 10 days; and minimum preharvest interval–66 days, except in California where no treatment may occur after bloom. These use patterns are consistent with residue data submitted in support of grapes, or typical use during the market basket survey.

21. *Kadota figs.* Maneb is registered for use on kadota figs. The Agency intends to cancel all maneb products registered for use on kadota figs unless the registrations and labelling are amended as follows: Maximum application rate–0.6 lb. a.i./100 gallons not to exceed 2.4 lb a.i./A; maximum number of applications per season–1; and minimum preharvest interval–10 days. This use pattern is consistent with available field trial residue data.

22. *Kale.* Maneb is registered for use on kale. The Agency intends to cancel all maneb products registered for use on kale unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–2 per cutting; application interval–7 to 10 days; and minimum preharvest interval–10 days. This use pattern is consistent with the typical use during the market basket survey period and is based on data submitted by commenters to the EBDC PD 2/3.

23. *Kohlrabi.* Maneb is registered for use on kohlrabi. The Agency intends to cancel all maneb products registered for use on kohlrabi unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–7 days. This use pattern is consistent with the typical use and residue data submitted in support of broccoli, which are translatable to kohlrabi.

24. *Lettuce, head.* Maneb is registered for use on head lettuce. The Agency intends to cancel all maneb products registered for use on head lettuce unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–6, except in California which must be no more than 4; application interval–7 to 10 days; and minimum preharvest interval–10 days, except in California which must be at least 14 days. This use pattern is consistent with the typical use during the market basket survey period, residue data submitted in support of lettuce, and information provided by commenters.

25. *Lettuce, leaf.* Maneb is registered for use on leaf lettuce. The Agency intends to cancel all maneb products registered for use on leaf lettuce unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–6, except in California which must be no more than 4; application interval–7 to 10 days; and minimum preharvest interval–10 days, except in California which must be at least 14 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of lettuce.

26. *Melons (cantaloupe, casaba, crenshaw, honeydew, and watermelon).* Mancozeb and maneb are registered for use on melons. The Agency intends to cancel all mancozeb products registered for use on melons unless the registrations and labelling are amended as follows: Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–8; application interval–7 to 10 days; and minimum preharvest interval–5 days. These use patterns are consistent with the typical use during the market basket survey period and residue data submitted in support of cucumbers, which are translatable to melons. The Agency intends to cancel all maneb products

registered for use on melons unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–8; application interval–7 to 10 days; and minimum preharvest interval–5 days.

27. *Oats.* Mancozeb is registered for use on oats. The Agency intends to cancel all mancozeb products registered for use on oats unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–3; application interval–7 to 10 days; and minimum preharvest interval–26 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of sweet corn, which are translatable to oats.

28. *Onions (dry bulb and green).* Maneb is registered for use on dry bulb and green onions. Mancozeb is registered for use on dry bulb onions. The Agency intends to cancel all mancozeb and maneb products registered for use on dry onions unless the registrations and labelling are amended as follows: Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–10; application interval–7 days; and minimum preharvest interval–7 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of onions. Also, the Agency intends to cancel all mancozeb and maneb products registered for use on onions unless the registrations and labelling are amended to include the following statement: "Do not apply to exposed bulbs." The Agency intends to cancel all maneb products registered for use on green onions unless the registrations and labelling are amended as follows: Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–7; application interval–7 days; and minimum preharvest interval–7 days.

29. *Papayas.* Mancozeb and maneb are registered for use on papayas. The Agency intends to cancel all mancozeb and maneb products registered for use on papayas unless the registrations and labelling are amended as follows: Maximum application rate–2.0 lb. a.i./A; maximum number of applications per season–14; application interval–14 to 21 days; and minimum preharvest interval–0 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of papayas.

30. *Peanuts.* Mancozeb is registered for use on peanuts. The Agency intends to cancel all mancozeb products registered for use on peanuts unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–8; application interval–7 to 14 days; and minimum preharvest interval–14 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of dry beans, which are translatable to peanuts.

31. *Pears.* Mancozeb is registered for use on pears. The Agency intends to cancel all mancozeb products registered for use on pears unless the registrations and labelling are amended as follows: All mancozeb products registered for use on pears must state that the product may be used with either the pre-bloom use pattern or the extended application use pattern. Further, the label must state that the two treatment schedules (i.e., pre-bloom and extended) must not be combined or integrated. The pre-bloom use pattern must be at least as restrictive as the following: Maximum application rate–4.8 lb. a.i./A; maximum number of applications per season–4; application interval–7 to 10 days; and minimum preharvest interval-bloom. The extended application use pattern must be at least as restrictive as the following: Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–7; application interval–7 to 10 days; and minimum preharvest interval–77 days. These use patterns are consistent with the International Apple Institute data on apples which were submitted in lieu of the required market basket survey data, and are translatable to pears. Additionally, to avoid cancellation, all mancozeb products registered for pears must include the following label statement: "It is recommended that this product be used in an Integrated Pest Management Program."

32. *Pecans.* No EBDC products are currently registered for use on pecans. EPA will allow metiram to be registered for use on pecans provided all applicable data requirements and other requirements of registration are met. As an additional condition of registration, any metiram product registered for use on pecans must be at least as restrictive as the following use pattern: Maximum application rate–6.4 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–5 weeks after petal fall.

33. *Peppers.* Maneb is registered for use on peppers. The Agency intends to cancel all maneb products registered for use on peppers grown west of the Mississippi River unless the registrations and labelling are amended such that the label must specify the following as applicable West of the Mississippi River: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–7 days. The Agency intends to cancel all maneb products registered for use on peppers grown east of the Mississippi River unless the registrations and labelling are amended such that the label must specify the following as applicable east of the Mississippi River: Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–7 days. These use patterns are consistent with the typical use during the market basket survey period and residue data submitted in support of tomatoes, which are translatable to peppers.

34. *Potatoes.* Mancozeb, maneb, and metiram are registered for use on potatoes. The Agency intends to cancel all mancozeb, maneb, or metiram products registered for use on potatoes unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–7; application interval–5 to 10 days; and minimum preharvest interval–3 days in Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Pennsylvania, Vermont, and Wisconsin and at least 14 days elsewhere. Also, in order to avoid cancellation, all mancozeb, maneb, and metiram labels must include the following label statement: "It is recommended that this product be used within an Integrated Pest Management Program. Also, vine-kill should occur 14 days before harvest." This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of potatoes. The label statement is consistent with public comments received on the EBDC PD 2/3.

35. *Pumpkins.* Maneb is registered for use on pumpkins. The Agency intends to cancel all maneb products registered for use on pumpkins unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–6; application interval–7 to 10 days; and minimum preharvest interval–5 days. These use patterns are consistent with the typical use during the market basket survey period and residue data submitted in support of cucumbers, which are translatable to pumpkins.

36. *Rye.* Mancozeb is registered for use on rye. The Agency intends to cancel all mancozeb products registered for use on rye unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–3; application interval–7 to 10 days; and minimum preharvest interval–26 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of sweet corn, which are translatable to rye.

37. *Squash.* Maneb is registered for both summer and winter squash while mancozeb only is registered for summer squash. The Agency intends to cancel all maneb products registered for use on summer or winter squash unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–8; application interval–7 to 10 days; and minimum preharvest interval–5 days. The Agency intends to cancel all mancozeb products registered for use on summer squash unless the registrations and labelling are amended as follows: Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–8; application interval–7 to 10 days; and minimum preharvest interval–5 days. These use patterns are consistent with the typical use during the market basket survey period and residue data submitted in support of cucumbers, which are translatable to squash.

38. *Sugar beets.* Mancozeb and maneb are registered for use on sugar beets. The Agency intends to cancel all mancozeb and maneb products registered for use on sugar beets unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–7; application interval–7 to 10 days; and minimum preharvest interval–14 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of sugar beets.

39. *Tomatoes.* Mancozeb and maneb are registered for use on tomatoes. The Agency intends to cancel all mancozeb and maneb products registered for use on tomatoes grown west of the Mississippi River unless the registrations and labelling are amended such that the label must specify the following as applicable west of the Mississippi River: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–4; application interval–7 to 10 days; and minimum preharvest interval–5 days. The Agency intends to cancel all mancozeb and maneb products registered for use on tomatoes grown east of the Mississippi River unless the registrations and labelling are amended such that the label must specify the following as applicable east of the Mississippi River: Maximum application rate–2.4 lb. a.i./A; maximum number of applications per season–7; application interval–7 to 10 days; and minimum preharvest interval–5 days. These use patterns are consistent with the typical use during the market basket survey period and residue data submitted in support of tomatoes.

40. *Wheat.* Mancozeb is registered for use on wheat. The Agency intends to cancel all mancozeb products registered for use on wheat unless the registrations and labelling are amended as follows: Maximum application rate–1.6 lb. a.i./A; maximum number of applications per season–3; application interval–7 to 10 days; and minimum preharvest interval–26 days. This use pattern is consistent with the typical use during the market basket survey period and residue data submitted in support of sweet corn, which are translatable to wheat.

41. *Apricots, carrots, celery, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, and turnips.* In order to avoid cancellation, any product registration and label bearing uses for apricots, celery, carrots, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, or turnips must be amended within the time specified in Unit VIII to delete each of these uses.

42. *Homegarden uses of mancozeb on fruit trees and turf.* In order to avoid cancellation, all mancozeb product registrations and labels bearing homegarden uses for fruit trees or turf must be amended to delete each of these two uses.

43. *Worker requirements for agricultural uses.* In order to avoid cancellation, all mancozeb, maneb, and metiram product registrations and labels bearing uses for agricultural uses must be amended to include the following protective clothing language: "All agricultural workers/handlers (i.e., mixers, loaders, and applicators) applying EBDCs must wear coveralls over long-sleeved shirt and long pants, shoes, socks, and chemical-resistant gloves. During mixing and loading, a chemical-resistant apron and goggles or a face shield must also be worn. For agricultural workers, where completely enclosed cabs with positive pressure filtration or an enclosed cockpit for aerial application are used, a long-sleeved shirt and long pants may be worn in place of the protective clothing described above. Chemical-resistant gloves must be available in the cab or cockpit and worn upon exiting. The gloves must be kept in an enclosed container in the cab or cockpit to prevent contamination of the inside of the cab or cockpit. During aerial application, human flaggers are prohibited unless in totally enclosed vehicles." Additionally, all mancozeb, maneb, and metiram product registrations and labels bearing agricultural uses must be amended to establish an interim reentry interval of 24 hours. This interim reentry interval will remain in effect until the Agency completes its evaluation of the reentry data. When the review is complete, the Agency will reestablish reentry intervals, if appropriate. No nabam labels bear any agricultural uses.

44. *Worker requirements for industrial uses.* In order to avoid cancellation, all nabam product registrations and labels bearing any industrial uses must be amended to include the following protective clothing language: "All industrial workers (i.e., mixers, loaders, and applicators) applying EBDCs must wear coveralls over a long-sleeved shirt and long pants, shoes, socks, and chemical-resistant gloves. During mixing and loading, a chemical-resistant apron and goggles or a face shield must also be worn." No mancozeb, maneb, or metiram labels can bear any industrial uses.

45. *Homegardener use requirements.* In order to avoid cancellation, all mancozeb (except those for fruit trees and turf), maneb, and metiram product registrations and labels bearing homegarden uses must be amended to bear the following clothing and hygiene language: "Homegardeners applying this product must wear a long-sleeved shirt, long pants, and chemical-resistant gloves. The gloves must be washed thoroughly with soap and water before removing. Clothes must be changed immediately after using this EBDC product and must be laundered separately from other laundry items before reuse."

C. Tolerance Reductions/Revocations

In May 1990, EPA proposed to reduce and revoke the tolerances for the 42 uses deleted by the technical registrants in September 1990 and for the 3 additional uses that the Agency proposed to cancel (55 FR 20416).

In view of the actions required by this Notice, EPA will continue its efforts to revoke mancozeb, maneb, and/or metiram tolerances for apricots, carrots, celery, collards, mustard greens,

nectarines, peaches, rhubarb, spinach, succulent beans, and turnips. The Agency expects to issue a Final Rule revoking the tolerances for these 11 commodities within 3 months of today's Notice and will allow for legally-treated commodities to clear the channels-of-trade.

For a number of sites, additional residue data may be needed to assess tolerances. EPA expects to issue within the next 6 months a Data Call-In (DCI) Notice under FIFRA section 3(c)(2)(B) to require any data that are determined to be needed for tolerance assessment purposes. Sites where it appears now that additional data may be required for use in assessing tolerances include: apples, kale, and pears. Where adequate data are available, the Agency will seek to adjust tolerances, where necessary, for the remaining 45 sites.

D. Existing Stocks and Disposal Provisions

1. *Non-conforming stocks.* Under the authority of FIFRA section 6, EPA may establish certain limitations on the sale, distribution, and use of existing stocks of EBDC pesticide products subject to any final cancellation Notice. EPA defines the term "existing stocks" to mean any quantity of EBDC pesticide product in the United States, on the date of cancellation which is being held for shipment or release or has been shipped or released into commerce.

EPA has determined that continued sale and distribution by the registrants of existing stocks of EBDC pesticides that do not comply with the provisions of this Notice may continue for 6 months following the date of cancellation. Existing stocks which are not sold or distributed by the registrants within that time period or are not properly relabelled in accordance with this Notice must be disposed of in accordance with applicable Federal, State, and local requirements. Sale and use by persons other than the registrants may continue for 3 years after the date of cancellation.

2. *Requirements for relabelling of existing stocks.* For the 1992 use season, the Agency will permit relabelling to occur by persons other than the registrants provided that those persons are acting under the supervision of the registrant. Supervision by the registrant does not have to be direct on-site supervision at the site where the relabelling is occurring. However, in cases where relabelling is performed, it must be performed by someone acting under the supervision of the registrant. The registrant will remain responsible and liable for the proper relabelling of the product. Additionally, for the purposes of this relabelling program, any such person acting on behalf of the registrant will be considered for the purposes of FIFRA to be an agent of the registrant of the product being relabelled. The relabelling may also be conducted at facilities that are not EPA registered establishments under FIFRA section 7, provided that the registrants comply with the reporting requirements in the following paragraph. After December 31, 1992, relabelling may only occur by the registrant or persons under contract to the registrant for the production of that pesticide and such relabelling must comply with FIFRA section 7.

Registrants must submit to EPA a report by June 30, 1992 concerning any relabelling of its product undertaken by any person under the terms of the above paragraph. A report must also be submitted to EPA by December 31, 1992 if any additional relabelling of EBDC product occurred since the June 30 report. These reports must identify the person or company that performed the relabelling; the registration number(s) of the product that was relabelled; the address of the facility where the relabelling took place; the date(s) on which the relabelling took place; and, for each registration number, the quantity of product relabelled. These reports must be filed with the Director of the Compliance Division; Office of Compliance Monitoring (EN–342); Environmental Protection Agency, 401 M Street, SW.; Washington, DC 20460. Failure to comply with the above relabelling or reporting requirements will be considered, among other things, a violation of FIFRA sections 12(a)(2)(K) and 12(a)(2)(N).

VIII. Procedural Matters

This Notice announces EPA's intent to cancel all registrations for products containing EBDCs which do not comply with the modified terms and conditions of registration set forth in this Notice. This action is being taken pursuant to authority granted by section 6(b) of FIFRA. Under FIFRA sections 6(b)(1) and 3(c)(6), applicants, registrants, and certain other adversely affected parties may request a hearing on the cancellation or denial actions that this Notice initiates. Any hearing concerning cancellation or denial of registration for any pesticide product containing the EBDCs will be held in accordance with FIFRA section 6(d). Alternatively, registrants/applicants may apply to amend the product registrations/applications to remove the uses proposed to be cancelled and make the other changes required by this Notice within 30 days of publication of this Notice or receipt of this Notice, whichever occurs later. Unless a hearing or amended registration is properly requested with regard to a particular registration or application, the registration will be cancelled or the application denied. This Unit of the Notice explains how such persons may request a hearing or amend their registrations in accordance with the procedures specified in this Notice, and the consequences of requesting or failing to request a hearing or submit an amended registration or application.

A. Procedures for Requesting a Hearing

To contest the regulatory action initiated by this Notice, registrants, or any applicant for registration whose application for registration is affected by this Notice (including intrastate applicants who have previously marketed such products pursuant to 40 CFR 162.17), must request a hearing within 30 days of receipt of this Notice, or within 30 days from the date of publication of this Notice in the **Federal Register**, whichever occurs later. Any other persons adversely affected by the cancellation action described in this Notice, or any interested persons with the concurrence of an applicant whose application for registration has been denied, must request a hearing within 30 days of publication of this Notice in the **Federal Register**.

All registrants, applicants, and other adversely affected persons who request a hearing must file the request in accordance with the procedures established by FIFRA and EPA's Rules of Practice Governing Hearings (40 CFR Part 164). These procedures require that all requests must identify the specific registration(s) by Registration Number(s) and the specific use(s) for which a hearing is requested and must be received by the Hearing Clerk within the applicable 30-day period. Failure to comply with these requirements will result in denial of the request for a hearing. Requests for a hearing should also be accompanied by objections that are specific for each use of the pesticide product for which a hearing is requested.Requests for a hearing must be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

1. *Consequences of filing a timely and effective hearing request.* If a hearing on any action initiated by this Notice is requested in a timely and effective manner, the hearing will be governed by EPA's Rules of Practice Governing Hearings under FIFRA section 6 (40 CFR part 164). All hearings will be held in Washington, DC. In the event of a timely

and effective request for a hearing, each cancellation action concerning the specific use or uses of the specific registered product which is the subject of the hearing request will not become effective except pursuant to an order of the Administrator at the conclusion of the hearing.

The hearing will be limited to the specific registrations or applications for which the hearing is requested.

2. *Consequences of failure to file in a timely and effective manner.* If a hearing concerning the cancellation or denial of registration of a specific EBDC product subject to this Notice is not requested in a timely and effective manner by the end of the applicable 30-day period, registration of that product will be cancelled or the denial will be effective.

B. Amendment of Registration or Application

Registrants of EBDC products who are affected by this Notice of Intent to Cancel (NOIC) may avoid cancellation of their registrations without requesting a hearing by filing an application for an amended registration to amend product labelling to comply with the labelling requirements described in Unit VII of this NOIC. Applications containing the label modifications required by this Notice must include 3 copies of the revised label. The approved label must be affixed to all end-use products released for shipment 6 months after publication of this Notice. All applications for amendment must be filed within 30 days of the date of **Federal Register** publication of this Notice or within 30 days of receipt of this Notice, whichever occurs later. Similarly applicants for a registration that is subject to this NOIC must file an amended application for registration within the applicable 30-day period to avoid denial of the application. The failure to file an amendment on time or the timely filing of an inadequate amendment will result in automatic cancellation pursuant to FIFRA section 6(b) or denial under section 3(c)(6).

Registrants whose registrations become cancelled but who wish to use the existing stocks provisions provided above must submit revised labelling, including proposed time limitations on use, for EPA acceptance prior to the sale and distribution of such existing stocks. All applications must be addressed to: Susan Lewis, Product Manager Number 21, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

C. Separation of Functions

EPA's rules of practice forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding ex parte with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of his/her representatives (40 CFR 164.7).

Accordingly, the following EPA offices, and the staffs thereof, are designated as the judicial staff of EPA to perform the judicial function of EPA in any administrative hearing on this Notice of Intent to Cancel: the Office of Administrative Law Judge, the Office of the Judicial Officer, the Deputy Administrator and the members of the staff in the immediate office of the Deputy Administrator, and the Administrator and the members of the staff in the immediate office of the Administrator. None of the persons designated as the judicial staff may have any ex parte communications on the merits of any of the issues involved in this proceeding with the trial staff or any other interested person not employed by EPA without fully complying with the applicable regulations.

D. Public Docket

Pursuant to 40 CFR 154.15, the Agency has established a public docket (OPP–30000/18D) for the EBDC Special Review. This public docket includes:

(1) this Notice; (2) any other notices pertinent to the EBDC Special Review; (3) non-CBI documents and copies of written comments or other materials submitted to the Agency in response to this Notice or any other Notice, and any other documents regarding the EBDC pesticides submitted at any time during the Special Review process by any person outside the government; (4) a transcript of any public meeting held by the Agency for the purpose of gathering information on the EBDCs; (5) memoranda describing each meeting held during the Special Review process between Agency personnel and any person outside government pertaining to the EBDCs; and (6) a current index of materials in the public docket.

IX. References

(1) Clifford, M.A. (1991). Memorandum to Kathleen Martin (USEPA). Apple Residue Field Trial Study. February 21, 1991.

(2) Hummel, S.V. (1991). Memorandum to Kathleen Martin (USEPA). EBDCs -Response to Special Review Data Call-In Notice of November 7, 1990. EBDC and ETU Residues in Apples from Field Trials Using Proposed New Use Pattern. May 23, 1991.

(3) Hummel, S.V. (1992). Memorandum to Kathleen Martin (USEPA). EBDCs -Response to Special Review Data Call-In Notice of November 7, 1990. EBDC and ETU Residues in Apples from Field Trials Using Second Proposed New Use Pattern. January 8, 1992.

(4) Hummel, S.V. (1991) Memorandum to Kathleen Martin (USEPA). Mancozeb Residues in Papayas; Commercial Handling Study Hawaii Papaya Industry Association. May 23, 1991.

(5) Hummel, S.V. (1990) Memorandum to Kathleen Martin (USEPA). EBDC/ETU Use Survey and Monitoring, 1989 Midwest Food Processors Association, Inc. November 28, 1990.

(6) Hummel, S.V. (1991). Memorandum to Kathleen Martin (USEPA). EBDCs -Response to PD 2/3 Comments. June 12, 1991.

(7) U.S. Environmental Protection Agency (USEPA). (1989) Data Call-In for the EBDCs. March 10, 1989.

(8) U.S. Environmental Protection Agency (USEPA). (1989) EBDC Technical Support Document.

(9)Kocialski, A. (1991). Memorandum to Kathleen Martin (USEPA). Third Peer Review of Ethylene Thiourea. Selecting the Q_1^* for Ethylenethiourea (ETU). September 26, 1991.

(10) Kocialski, A. (1991). Memorandum to Kathleen Martin (USEPA). Ethylenethiourea Cancer Potency Factor (Q_1^*) Calculations Based on Female Mouse Liver Tumors Using Both Pooled Data and the Diagonal Data Set from the National Toxicology Program Study (NTP–TR–No.388).

(11) Noles, J. (1991). Memorandum to Kathleen Martin (USEPA). Addendum to the June 1, 1990 Summary of Data Submitted After Publication of the Registration Standards for Mancozeb, Maneb, Metiram and Nabam.

(12) Kocialski, A. (1991). Memorandum to Kathleen Martin (USEPA). EBDC/Responses to Toxicology Comments on Position Document 2/3.

(13) ETU Task Force. (1990). EBDC/ETU National Food Survey Fourth Quarter and Final Report. October 1, 1990. USEPA MRID No. 416436–01.

(14) Clifford, M.A. (1991). Memorandum to Kathleen Martin (USEPA). The Statistical Issues of the EBDC/ETU Market Basket Survey. January 14, 1991.

(15) Clifford, M.A. (1991). Memorandum to Kathleen Martin (USEPA). Review of EBDC/ETU Market Basket Data, Statistical Issues. April 22, 1991.

(16) Clifford, M.A. (1991). Memorandum to Kathleen Martin (USEPA). The Results from the EBDC/ETU Market Basket Survey and Final Review of the Statistical Issues Concerning the Survey. April 22, 1991.

(17) Hummel, S.V. (1991). Memorandum to Kathleen Martin (USEPA). EBDCs -Dietary Exposure Estimates for EBDCs and ETU Based on the EBDC/ETU Market Basket Survey. February 28, 1991.

(18) Hummel, S.V. (1990). Memorandum to Kathleen Martin (USEPA). EBDC/ETU Monitoring Study Fourth Quarter and Final Report. December 4, 1990.

(19) Hummel, S.V. (1989). Memorandum to Kathleen Martin (USEPA). EBDC Monitoring Study Translation of Data. December 11, 1989.

(20) Hummel, S.V. (1991). Memorandum to Kathleen Martin (USEPA). EBDCs -Response to Special Review Data Call-In Notice of November 7, 1990. EBDC and Residues in Bananas Collected at Ports of Entry into the US. May 20, 1991.

(21) Hummel, S.V. (1991). Memorandum to Kathleen Martin (USEPA). EBDCs -Response to Special Review Data Call-In Notice of November 7, 1990. EBDC and ETU Residues in Grape Juice Collected in Areas Likely to Have Been Treated with EBDCs. May 20, 1991.

(22) Hummel, S.V. (1991). Memorandum to Kathleen Martin (USEPA). EBDCs -Response to Special Review Data Call-In Notice of November 7, 1990. EBDC and ETU Residues in Grape Wine Collected in Areas Likely to Have Been Treated with EBDCs.

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(32) Jennings, A.L. (1991) Revised Site Analyses for the Benefits of EBDCs for the PD 4. Biological and Economic Analysis Division, OPP, USEPA. November 1991.

(33) Griffin, R. (1991). Memorandum to Kathleen Martin (USEPA). EBDC/ETU Special Review. DRES Dietary Exposure/Risk Estimates. October 11, 1991.

(34) Griffin, R. (1991). Memorandum to Kathleen Martin (USEPA). EBDC/ETU. Preliminary Carcinogenic Risk Estimates Based (In Part) on Market Basket Survey Data. March 1, 1991.

(35) Griffin, R. (1992). Memorandum to Kathleen Martin (USEPA). EBDC/ETU Special Review. DRES Dietary Exposure/Risk Estimate Revisions for Apples and Pears. January 10, 1992.

(36) Griffin, R. (1991). Memorandum to Kathleen Martin (USEPA). Response to EBDC/ETU Public Comment. June 20, 1991.

(37) Knott, S.M. (1991). Memorandum to Kathleen Martin (USEPA). Updated Occupational and Residential Exposure Assessment for the EBDC Final Determination. December 10, 1991.

(38) Zendzian, R. (1991). Memorandum to Kathleen Martin (USEPA). EBDCs -Dermal Absorption of ETU. February 16, 1991.

(39) Knott, S.M. (1991). Memorandum to Kathleen Martin (USEPA). Update on the EBDC Occupational and Residential Exposure Assessment, Comments, and Tank-Mix Stability Study Settlement Agreement. August 21, 1991.

(40) Knott, S.M. (1991). Memorandum to Kathleen Martin (USEPA). Review of Rebuttal Comments on the Preliminary Determination to Cancel Certain EBDC Registrations. May 16, 1991.

(41) The American Pyhtopathological Society. Fungicide and Nematicide Tests. St. Paul, Minnesota.

All but the published references concerning this Final Determination on the EBDCs are available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in the Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, room 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Dated: February 13, 1992.

Linda J. Fisher,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 92-4772 Filed 2-28-92; 8:45 am]

Billing Code 6560-50-F

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At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

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CFR CHECKLIST

This checklist, prepared by the Office of the Federal Register, is published weekly. It is arranged in the order of CFR titles, stock numbers, prices, and revision dates.

An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

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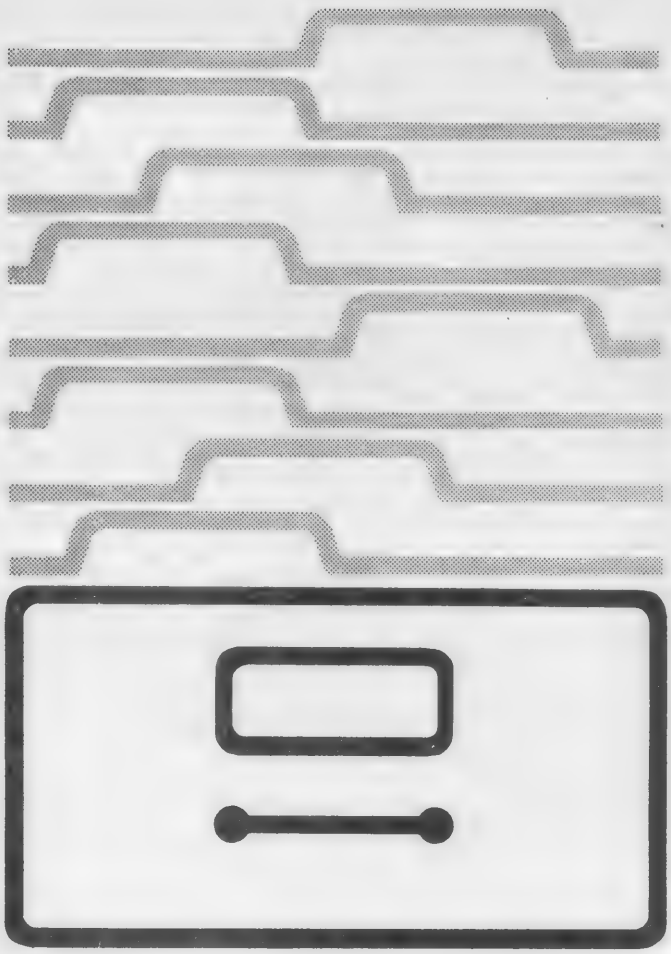

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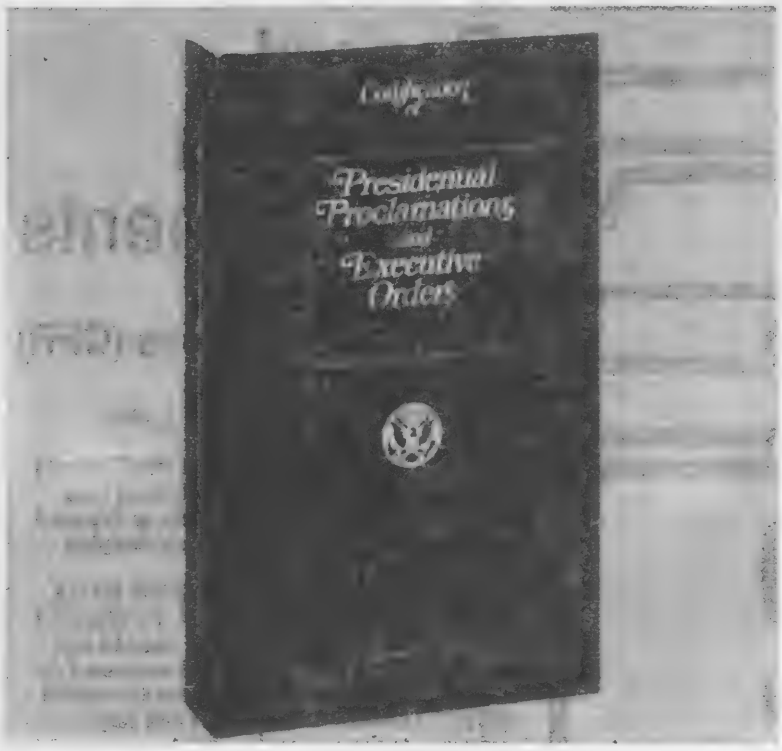

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